Underwriters Laboratories (UL LLC)
Safety Certification Body (CB) Report

Model:	GT*96600-**-** The 1st "*" part can be 'M' or '-' or 'H' for market identification and not related to safety. The 2nd "*" denotes the rated output wattage designation, which can be "01" to "65", with interval of 1. The 3rd"*" denote the standard rated output voltage designation, which can be "05" to "54" or "5.0" to "54.0" in 0.1V increments. The 4th"*" can be "T2', "T2A", "T3", " T3A", "T2L", "T2AL", "T3L", " T3AL", "R2", "R3A", "P2", "P3", "TP", "TP3", "TW", "TW3", "T2" means desktop class II with C8 AC inlet, "T2A" means desktop class II with C18 AC inlet, "T3" means desktop class II with functional earth with C14 AC inlet, "T3A" means desktop class II with functional earth with C6 AC inlet, "T2L" means desktop class II with C8 AC inlet and housing with a DC jack, "T2AL" means desktop class II with C18 AC inlet and housing with a DC jack, "T3L" means desktop class II with functional earth with C14 AC inlet and housing with a DC jack, "T3AL" means desktop class II with functional earth with C6 AC inlet and housing with a DC jack, "R2" means hybrid desktop housing class II with C8 AC inlet, "R3A" means hybrid desktop housing class II with functional earth with C6 AC inlet, "P2" means Encapsulated class II, "P3" means Encapsulated class II with functional earth, "TP" means desktop class II with power supply cord with plug, "TP3" means desktop class II with functional earth with power supply cord with plug, "TW" means desktop class II with input wire without plug, "TW3" means desktop class II with functional earth with input wire without plug. The last * denote any six characters = 0-9 or A-Z or ()[] or – or blank for marketing purposes.
Device Description:	Medical Power Supply
Applicant:	GLOBTEK (HONG KONG) LTD UNIT 1402, BENSON TOWER, 74 HUNG TO RD KWUN TONG, KOWLOON, HONGKONG
Manufacturer:	Same as Applicant
Manufacturing Facility(ies):	GLOBTEK (SUZHOU) CO LTD BLDG 4, #76 JINLING EAST RD SUZHOU PARK SUZHOU JIANGSU 215021 China
Report No.:	E341350-D1012-1/A0/C0-CB
Report (Re)Issue Date:	2025-01-14
Base Standard(s):	IEC 60601-1:2005, AMD1:2012, AMD2:2020
Additional Standards:	ANSI/AAMI ES60601-1:2005 & A1:2012 & A2:2021, CAN/CSA-C22.2 NO. 60601-1:14 AMD2:2022, IEC 60601-1-11:2015/AMD1, IEC 60601-1-6:2010, AMD1:2013, AMD2:2020:2020, EN 60601-1:2006+A1:2013+A12:2014+A2:2021
Report Types:	This report consists of the following report types: - CB Report & Certificate

This report covers the Safety evaluation of the referenced model(s) according to the standard(s) specified above.

The **CB Certificate** is provided as a separate enclosure to this report and not provided in the body of this report.

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Report Modifications Summary

The following changes were made to this report. If none listed in the below table, this report is the originally issued report.

The following scheme is used throughout this report to reflect the **Report No.**:

(File No.) – (Report Ref. No.) – (x) / A(y) / C(z) – YYY, where:
(x) = Report (Re)Issue No.
(y) = Amendment No.
(z) = Correction No.
YYY = Report Type (UL/CB/IEC)

*NOTE: The **CB Certificate** may not be updated for report corrections that don't affect the CB Certificate contents; therefore if this report includes a correction number (z), it may not be reflected in the CB Certificate.*

Date Modified *(Year-Month-Day)*	Modifications Made (include Report Reference Number)	Modified By
2025-01-14	E341350-D1012-1/A0/C0-CB original report	Skye Mo

Test Report issued under the responsibility of:

TEST REPORT
IEC 60601-1
Medical Electrical Equipment
Part 1: General requirements for basic safety and essential performance

Report Number. .....:	E341350-D1012-1/A0/C0-CB
Date of issue .....:	2025-01-14
Total number of pages.....:	187
Name of Testing Laboratory preparing the Report.....:	UL-CCIC Company Limited Guangzhou Branch / Room 101 & 401, Block A, R&D Building, Room 101, 201, 301, & 401, Block B, Electronic Building, No.8, Nanyun Er Road, Huangpu District Guangzhou China
Applicant's name.....:	GLOBTEK (HONG KONG) LTD
Address .....:	UNIT 1402, BENSON TOWER, 74 HUNG TO RD KWUN TONG, KOWLOON, HONGKONG
Test specification:	
Standard.....:	IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
Test procedure .....:	CB Scheme
Non-standard test method……..:	N/A
TRF template used. .....:	IECEE OD-2020-F1:2020, Ed.1.3
Test Report Form No.....:	IEC60601_1U
Test Report Form(s) Originator ....:	UL(US)
Master TRF.....:	2023-08-24

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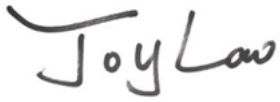
This report is not valid as a CB Test Report unless signed by an approved IECEE Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

General disclaimer:

The test results presented in this report relate only to the object tested.
This report shall not be reproduced, except in full, without the written approval of the Issuing NCB. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.

Test item description.....:	Medical Power Supply
Trade Mark(s) .....:	GlobTek, Inc.
Manufacturer .....:	Same as Applicant
Model/Type reference.....:	GT*96600-**-** The 1st "*" part can be 'M' or '-' or 'H' for market identification and not related to safety. The 2nd "*" denotes the rated output wattage designation, which can be "01" to "65", with interval of 1. The 3rd"*" denote the standard rated output voltage designation, which can be "05" to "54" or "5.0" to "54.0" in 0.1V increments. The 4th"*" can be "T2', "T2A", "T3", " T3A", "T2L", "T2AL", "T3L", " T3AL", "R2", "R3A", "P2", "P3", "TP", "TP3", "TW", "TW3", "T2" means desktop class II with C8 AC inlet, "T2A" means desktop class II with C18 AC inlet, "T3" means desktop class II with functional earth with C14 AC inlet, "T3A" means desktop class II with functional earth with C6 AC inlet, "T2L" means desktop class II with C8 AC inlet and housing with a DC jack, "T2AL" means desktop class II with C18 AC inlet and housing with a DC jack, "T3L" means desktop class II with functional earth with C14 AC inlet and housing with a DC jack, "T3AL" means desktop class II with functional earth with C6 AC inlet and housing with a DC jack, "R2" means hybrid desktop housing class II with C8 AC inlet, "R3A" means hybrid desktop housing class II with functional earth with C6 AC inlet, "P2" means Encapsulated class II, "P3" means Encapsulated class II with functional earth, "TP" means desktop class II with power supply cord with plug, "TP3" means desktop class II with functional earth with power supply cord with plug, "TW" means desktop class II with input wire without plug, "TW3" means desktop class II with functional earth with input wire without plug. The last * denote any six characters = 0-9 or A-Z or ()[] or – or blank for marketing purposes.
Ratings.....:	Input: 100-240Vac or 100-120Vac (for TP/TP3 models with NA standard plug), 50-60Hz, 1.5A Output: 5-54VDC, Max. 65W

Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):			
[X]	**CB Testing Laboratory:**		
Testing location/ address ..... :		UL-CCIC Company Limited Guangzhou Branch / Room 101 & 401, Block A, R&D Building, Room 101, 201, 301, & 401, Block B, Electronic Building, No.8, Nanyun Er Road, Huangpu District Guangzhou China	
Tested by (name, function, signature) ..... :		Skye Mo, Project handler	Skye Mo

Approved by (name, function, signature) .. :	Joy Lao, Project reviewer	
[ ] **Testing procedure: CTF Stage 1:**		
Testing location/ address ..... :		
Tested by (name, function, signature) ..... :		
Approved by (name, function, signature) .. :		
[ ] **Testing procedure: CTF Stage 2:**		
Testing location/ address ..... :		
Tested by (name, function, signature) ..... :		
Witnessed by (name, function, signature) . :		
Approved by (name, function, signature) .. :		
[ ] **Testing procedure: CTF Stage 3:**		
[ ] **Testing procedure: CTF Stage 4:**		
Testing location/ address ..... :		
Tested by (name, function, signature) ..... :		
Witnessed by (name, function, signature) . :		
Approved by (name, function, signature) .. :		
Supervised by (name, function, signature) :		

List of Attachments (including a total number of pages in each attachment):

Refer to Appendix A of this report. All attachments are included within this report.

Summary of testing:

Tests performed (name of test and test clause):	**Testing location:**
Refer to the Test List in Appendix B of this report if testing was performed as part of this evaluation.	*Refer to the Test List in Appendix B of this report if testing was performed as part of this evaluation.*

Summary of compliance with National Differences (List of countries addressed):

List of countries addressed: United States of America, Canada, EU Group (No Group Differences declared)

[X] The product fulfils the requirements of AAMI ES60601-1:2005,ES60601-1:2005/AMD1:2012 , ES60601-1:2005/AMD2:2021, CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14, EN 60601-1:2006+A1:2013+A12:2014+A2:2021.

Statement concerning the uncertainty of the measurement systems used for the tests

(may be required by the product standard or client)

[ ] **Internal procedure used for type testing through which traceability of the measuring uncertainty has been established:**

Procedure number, issue date and title:

Calculations leading to the reported values are on file with the NCB and testing laboratory that conducted the testing.

[X] **Statement not required by the standard used for type testing**

(Note: When IEC or ISO standard requires a statement concerning the uncertainty of the measurement systems used for tests, this should be reported above. The informative text in parenthesis should be delete in both cases after selecting the applicable option)

Copy of marking plate

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

Refer to the enclosure(s) titled Marking Label in the Enclosures section in Appendix A of this report for a copy.

Test item particulars ..... :	
Classification of Installation and Use:	Portable
Supply Connection:	To be evaluated in end product
Device type (component/sub-assembly/ equipment/ system):	Component
Intended use (Including type of patient, application location):	Power supplies used in medical device
Mode of Operation:	Continuous
Accessories and detachable parts included:	None
Other Options Include:	N/A
Supply Connection	
Possible test case verdicts:	
- test case does not apply to the test object .....:	N/A
- test object does meet the requirement .....:	P (Pass)
- test object was not evaluated for the requirement..... :	N/E (collateral standards only)
- test object does not meet the requirement .....:	F (Fail)
Abbreviations used in the report:	
- normal condition.....: N.C.	- single fault condition.....: S.F.C.
- means of Operator protection .....: MOOP	- means of Patient protection ....: MOPP
Testing.....:	
Date of receipt of test item .....:	2024-08-08, 2024-09-09, 2024-10-08, 2024-11-25, 2024-12-24
Date(s) of performance of tests .....:	2024-08-29 to 2024-09-29, 2024-10-09 to 2024-10-25, 2024-12-03 to 2025-01-02

General remarks:

"(See Enclosure #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:

The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided	Not Applicable

When differences exist; they shall be identified in the General product information section.

Name and address of factory (ies)..... :	GLOBTEK (SUZHOU) CO LTD BLDG 4, #76 JINLING EAST RD SUZHOU PARK SUZHOU JIANGSU 215021 China

General product information and other remarks:

Report Summary

The manufacturer submitted representative production sample of Medical Power Supply, Models GTM96600-4005-TP3, GTM96600-6019-T3, GTM96600-6554-TP, GTM96600-6554-TP3, GTM96600-6554-P2, GTM96600-6554-R2, GTM96600-4005-R2, for construction review and testing by UL staff. Due to

product similarity, most tests were conducted on Models GTM96600-4005-TP3, GTM96600-6019-T3, GTM96600-6554-TP, GTM96600-6554-TP3, GTM96600-6554-P2 as representative. IEC60601-1-11 tests were conducted only for Class II without functional earth construction. All of the tests were conducted at UL-CCIC Company Limited Guangzhou Branch Office, locates at Room 101 & 401, Block A, R&D Building, Room 101, 201, 301, & 401, Block B, Electronic Building, No.8, Nanyun Er Road, Huangpu District. The results of this investigation, including construction review and testing, indicate that the products evaluated comply with the applicable requirements in the standards.
All applicable tests according to the referenced standard(s) have been carried out.
Refer to the Report Modifications for any modifications made to this report.

Product Description

The equipment is a Medical Power Supply with electronic components mounted on PWB and housed in V-0 plastic enclosure with Class I/II AC inlet or power supply cord or input wire without plug. This unit is intended for general use as a component power supply of medical electrical equipment and systems.

Model Differences

All modes in their respective series are identical to each other except for model name, output rating, the secondary winding of the transformer (T1), input AC inlet and case size (117.5 by 53.5 by 34.2mm for desktop model, 114.6 by 54.1 by 36.6mm for hybrid desktop housing, 114.81 by 57.11 by 39mm for Encapsulated model) and a few non-critical components that used to adjust the output.
When the model is F3 INSULATION DIAGRAM, the Bridge Y-Capacitors is Max. 1500 pF. There are two types of PCB Layout. PCB layout version 1 is for F1/F2/F3 insulation diagram with C22 R33 CY3 reserved part. PCB layout version 2 is for F1/E2/F2 insulation diagram with R32 reserved part.
Desktop models have a copper foil and mylar on the Bottom Case.
Hybrid desktop models have a mylar on the Bottom Case.
Input rating 100-120Vac is for TP/TP3 models with NA standard plug, 100-240Vac is for other models.
See enclosure Miscellaneous-(001) and (002) for details.

Additional Information

Insulation construction E2, F2, F3 are for Class II models with functional earth.
IEC60601-1-11 evaluated for Class II insulation construction F1 without functional earth models only.

Technical Considerations

- The product was investigated to the following standards:

  Main Standard(s):

  IEC 60601-1:2005, AMD1:2012, AMD2:2020

  From Country Differences:

  - United States of America: AAMI ES60601-1:2005,ES60601-1:2005/AMD1:2012 , ES60601-1:2005/AMD2:2021
  - Canada: CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14

  Additional Standards:

  ANSI/AAMI ES60601-1:2005 & A1:2012 & A2:2021, CAN/CSA-C22.2 NO. 60601-1:14 AMD2:2022, IEC 60601-1-11:2015/AMD1, IEC 60601-1-6:2010, AMD1:2013, AMD2:2020:2020, EN 60601-1:2006+A1:2013+A12:2014+A2:2021

- The following additional investigations were conducted: None
- The product was not investigated to the following standards or clauses: Clause 17

Electromagnetic Compatibility(IEC 60601-1-2), Clauses 14 PEMS, Clause 11.7

Biocompatibility(ISO 10993)

- The following accessories were investigated for use with the product: N/A
- N/A

Engineering Conditions of Acceptability

When installed in an end-product, consideration must be given to the following:

This power supply has been judged on the basis of the required creepage and Clearances in the Standard for Medical Electrical Equipment, ANSI/AAMI ES 60601-1, Sub clause 8.9, and CAN/CSA-C22.2 No. 60601-1.

This power supply has been evaluated as Class II with or without functional earth, continuous operation, ordinary equipment and has not been evaluated for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. Additional evaluation shall be made if the power supply is intended for use in other condition.

This power supply was tested on a 20A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.

The power supply was evaluated as 2 MOPP between Primary to Secondary and 1 MOOP insulation provided between the opposite polarities of mains. See insulation diagram for details.

This power supply is evaluated operated up to 5000m above sea level as declared by manufacturer. Maximum ambient temperature for this power supply is 40 degree C.

Supply connection has three types of connections: AC inlet, power supply cord, input wire without plug, supply connection shall be evaluated in end-product.

Temperature limit of external enclosure is 86 degree C while duration of contact was defined as <1s. Further evaluation shall be considered in end product if other than this.

Consideration should be given to measure the temperatures on power electronic components and transformer windings when the power supply is installed in the end-use equipment.

Working voltage was conducted using case 2 according to the customer request.

The transformer (T1) incorporates a Class 130 (B) insulation system. The reference voltage for Dielectric Voltage Test of T1 is 240 Vrms, 387 Vpk.

The end-product evaluation shall ensure that the requirements related to Accompanying Documents, Clause 7.9 are met.

The output circuit has not been evaluated for patient connected application. The output circuit is SELV and is not at hazardous energy level.

The following tests shall be reconsidered in the end-product evaluation: Legibility Test, Temperature Test, Dielectric Voltage Withstand Tests and Leakage Current test.

End product Risk Management Process to consider the need for simultaneous fault condition testing.

End product to determine the acceptability of risk in conjunction to the Cleaning and Disinfection Methods as part of the power supply.

End product to determine the acceptability of risk in conjunction to the results of Mechanical Testing conducted as part of the power supply.

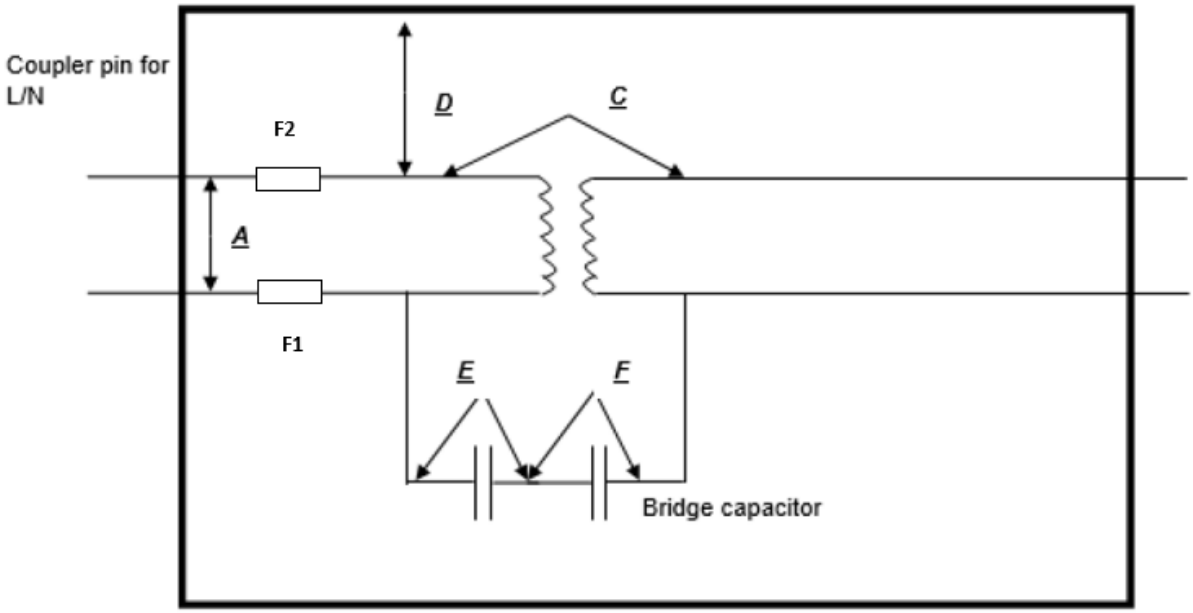
End product to determine the acceptability of risk evaluation in conjunction to the selection of components as it pertains to the intended use, essential performance, transport, storage conditions as part of the power supply.

Report Modifications

Date Modified *(Year-Month-Day)*	Modifications Made (include Report Reference Number)	Modified By
2025-01-14	E341350-D1012-1/A0/C0-CB original report	Skye Mo

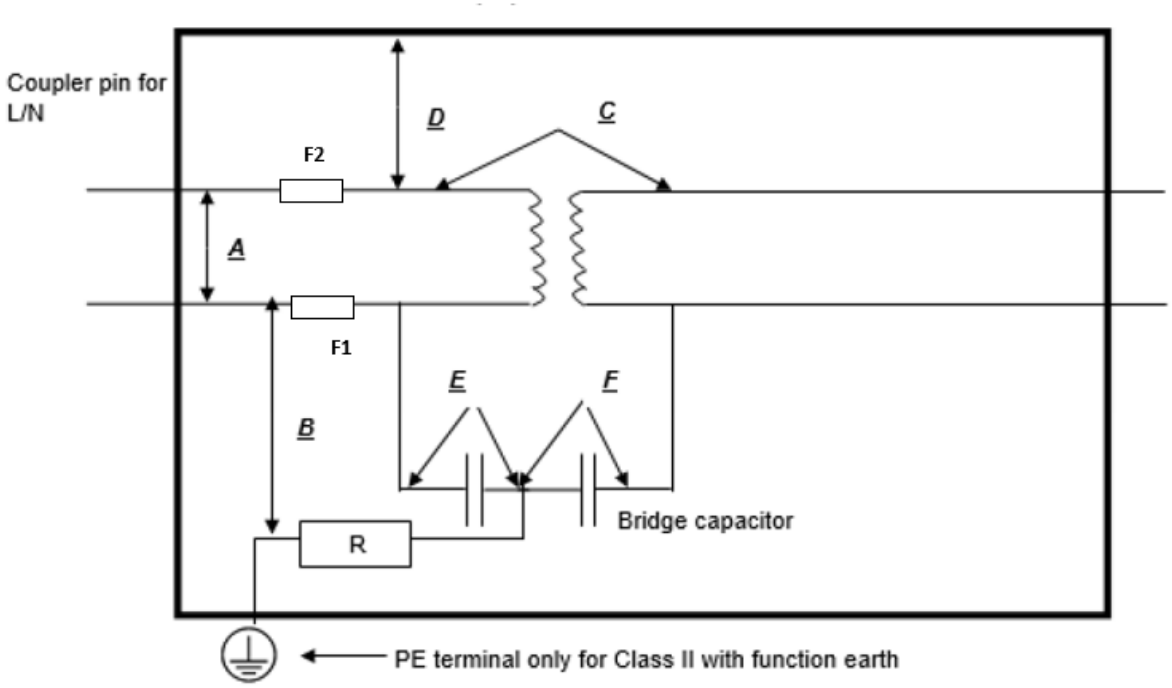
Insulation Diagram - (001) 001. Class II with F1 insulation construction

Insulation Diagram - (001) 001. Class II with F1 insulation construction



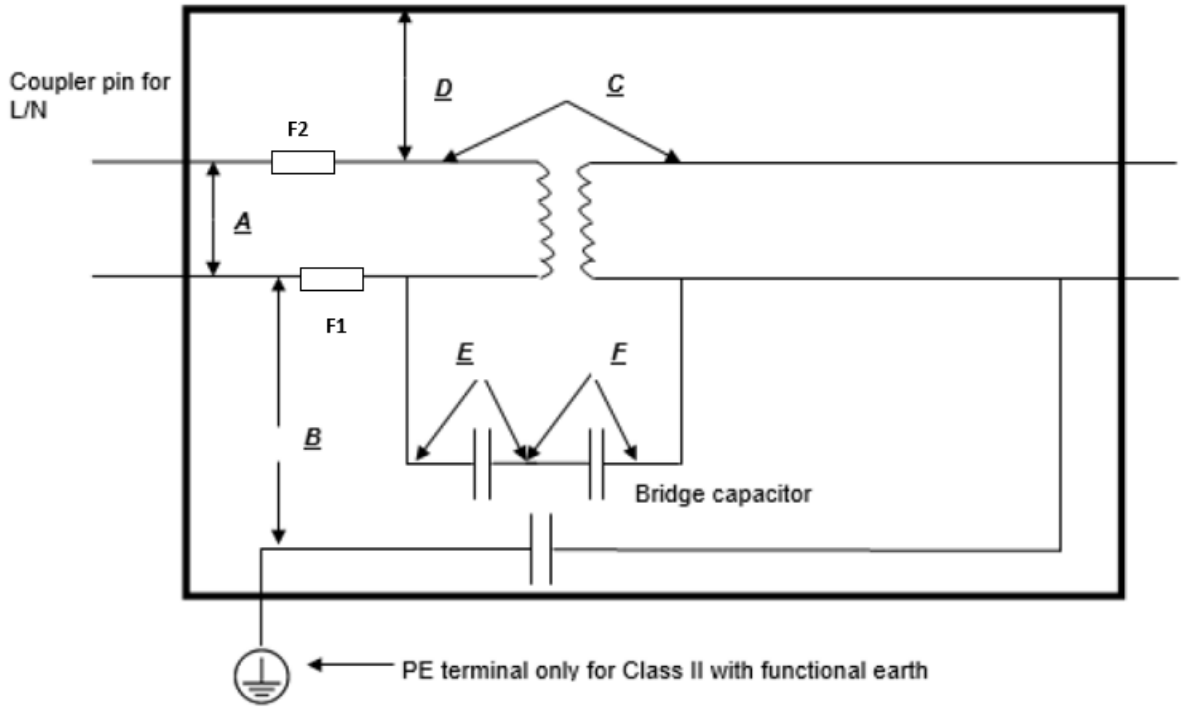
Insulation Diagram - (002) 002. Class II with F2 insulation construction

Insulation Diagram - (002) 002. Class II with F2 insulation construction



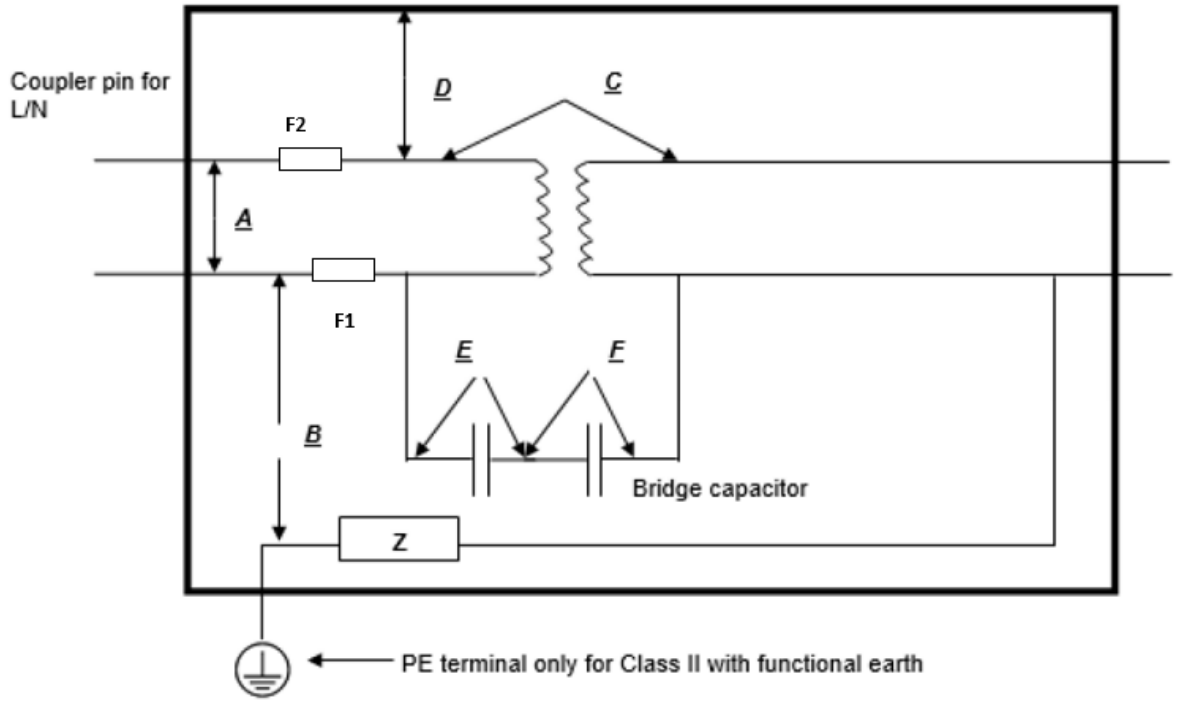
Insulation Diagram - (003) 003. Class II with F3 insulation construction

Insulation Diagram - (003) 003. Class II with F3 insulation construction



Insulation Diagram - (004) 004. Class II with E2 insulation construction

Insulation Diagram - (004) 004. Class II with E2 insulation construction



IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

TABLE: INSULATION DIAGRAM									Pass
Pollution Degree:		**2**							-
Overvoltage category:		**II**							-
Altitude:		**5000 (m)**							-
Additional details on parts considered as applied parts:		**[X] None [ ] Areas: (See Clause 4.6 for details)**							-
Area	**Number and type of Means of Protection: MOOP,MOPP**	**CTI**	**Working Voltage**		**Required creepage (mm)**	**Required clearance (mm)**	**Measured creepage (mm)**	**Measured clearance (mm)**	**Remarks**
			V_{rms}	**V_{pk}**					
A	1 MOOP	III b	240	340	2.96	2.96	10.6	10.6	L-N before fuses on PCB board
B*	1 MOPP	III b	240	340	4	3.225	**> 5.2	**> 5.2	L/N to PE terminal trace (floating for class II E2, F2, F3 construction, shall be evaluated in end-product)
C	2 MOPP	III b	240	340	7.9	6.45	8	7.7	Pri. circuit to Sec. circuit on PCB under U4
C	2 MOPP	III b	240	340	7.9	6.45	8	8	Pri. circuit to Sec. circuit on U4 body
C	2 MOPP	III b	240	387	7.9	6.45	10.1	10.1	Between T1 pri. winding to sec. component R25
C	2 MOPP	III b	240	387	7.9	6.45	**> 10.3	**> 10.3	T1 primary coil to secondary windings (TIW)
D	2 MOPP	III b	240	340	7.9	6.45	**> 10.3	**> 10.3	Between Pri. Circuit to plastic enclosure
E	1 MOPP	III b	240	340	4	3.225	4.2	4.2	Between CY1
E	1 MOPP	III b	240	340	4	3.225	-	-	Between CY2
F	1 MOPP	III b	240	340	4	3.225	4.2	4.2	Between Primary HS1 to CY1/CY2 pin, HS1 wraps 2 layers of insulation tapes
F	1 MOPP	III b	240	340	4	3.225	-	-	Between secondary HS2 to CY1/CY2 pin, heat shrinkable tube provided on HS2

Supplementary Information:
The medical power supplies are rated to operate at an altitude up to 5000m, the multiplication factors for AIR CLEARANCES is 1.29 for MOPP.
*: Aera B is for E2, F2, F3 construction only.

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Clause	Requirement + Test	Result - Remark	Verdict

**: ">" being used according to OD 2020 edition 4.0 clause 5.6.1.

INSULATION DIAGRAM CONVENTIONS and GUIDANCE:
A measured value must be provided in the value columns for the device under evaluation. The symbol > (greater than sign) must not be used. Switch-mode power supplies must be re-evaluated in the device under evaluation therefore N/A must not be used with a generic statement that the component is certified. Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:
- All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.
- Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional
- Applied parts are extended beyond the equipment enclosure and terminated with an arrow.
- Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.

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4	**GENERAL REQUIREMENTS**		Pass
4.1	**Requirements of this standard applied in normal use and reasonably foreseeable misuse**		N/A
4.2	**risk management process for me equipment or me systems**		Pass
4.2.2	**General requirement for risk management - process complies with ISO14971 (2019)** .....:	See Appended RM Results Table 4.2.2.	Pass
4.2.3	**Evaluating RISK**		Pass
4.2.3.1	**a) Compliance with the standard reduces residual risk to an acceptable level**		Pass
	b) Manufacturer has defined risk acceptability criteria in the risk management plan.....:	Risk management plan Document: GT-RMPLAN2013-010, version A.2, chapter 1.3	Pass
	c) When no specific technical requirements provided manufacturer has determined hazards or hazardous situations exists.		Pass
	- hazards or hazardous situations have been evaluated using the risk management process.		Pass
4.2.3.2	**manufacturer has addressed hazards or hazardous situations not specifically addressed in the IEC 60601-1 series.**		Pass
4.3	**Performance of clinical functions necessary to achieve intended use or that could affect the safety of the me equipment or me system were identified during risk analysis.**	Component, to be evaluated in end product	N/A
	- Performance limits were identified in both normal condition and single fault condition.		N/A
	- Loss or degradation of performance beyond the limits specified by the manufacturer were evaluated		N/A
	- Functions with unacceptable risks are identified as essential performance .....:		N/A
	- Risk control measures implemented		N/A
	- Methods used to verify the effectiveness of risk control measures implemented		N/A
4.4	**Expected service life stated in risk management file** .....:	10 years	Pass
4.5	**Alternative RISK CONTROL methods utilized** ...:	No such methods	N/A
	residual risk resulting from the alternative risk control measures or tests is acceptable and comparable to residual risk resulting from application of this standard: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Alternative means based scientific data or clinical opinion or comparative studies.....:		N/A
4.6	**Risk management process identifies parts that can come into contact with patient but not defined as applied parts, subjected to the requirements for applied parts, except for Clause 7.2.10**.....:	Component, to be evaluated in end product	N/A
	manufacturer assesses the risk of accessible parts coming into contact with the patient: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)		N/A
	Assessment identified the applied part type requirements.....:		N/A
4.7	**Me equipment remained single fault safe, or the risk remained acceptable as determined by Clause 4.2**.....:	Component Power Supply remained Single Fault Safe	Pass
	manufacturer risk analysis was used to determine failures to be tested: (ISO 14971 Cl. 5.2-5.5)		N/A
	Failure of any one component at a time that could result in a hazardous situation, including those in 13.1, simulated physically or theoretically.....:	See appended Table 13.2 for simulated physical test	Pass
4.8	**All components and wiring whose failure could result in a hazardous situation used according to their applicable ratings, unless specified**.....:	All components are used within their specified ratings	Pass
	Components and wiring exception in the standard or by risk management process		N/A
	risk management process assesses components to identify components where the failure results in a hazardous situation for components used outside their ratings: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)		N/A
	manufacturer identified components where the failure results in a hazardous situation.....:		N/A
	Components determined to be acceptable where used as a means of protection .....:		N/A
	Reliability of components used as means of protection assessed for conditions of use in me equipment, and they complied with one of the following		Pass
	a) Applicable safety requirements of a relevant IEC or ISO standard		Pass
	b) Requirements of this standard applied in the absence of a relevant IEC or ISO standard		Pass
4.9	**A component with high-integrity characteristics provided and selected appropriately**.....:	No such component	N/A

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Clause	Requirement + Test	Result - Remark	Verdict

	risk management file includes an assessment to determine if the failure of components results in unacceptable risk: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)		N/A
	Components identified and required to be components with high integrity characteristic..:		N/A
4.10	**Power supply**		Pass
4.10.1	**Me equipment is suitable for connection to indicated power source (select applicable)**.....:	Supply mains	Pass
4.10.2	**Maximum rated voltage for me equipment intended to be connected to supply mains** .....:		Pass
	- 250 V for hand-held me equipment (V).....:		N/A
	– 250 V d.c. or single-phase a.c., or 500 V poly-phase a.c. for me equipment and me systems with a rated input ≤ 4 kVA (V).....:	100-240V~ or 100-120Vac (TP/TP3 models with NA standard plug), single-phase	Pass
	– 500 V for all other me equipment and me systems		N/A
4.11	**Power input**		Pass
	Steady-state measured input of me equipment or me system at rated voltage or voltage range and at operating settings indicated in instructions for use didn't exceed marked rating by more than 10%.....:	See appended Table 4.11	Pass
5	**GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT**		Pass
5.1	**Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods**.....:	Test performed	N/A
	risk management file identifies combinations of simultaneous independent faults that could result in a hazardous situation. (ISO 14971 Cl. 5.2-5.5)		N/A
5.3	**Tests conducted within the environmental conditions specified in technical description**		Pass
	Temperature (ºC), Relative Humidity (%) .....:	-20 to 40 °C, ≤ 95%	-
	Atmospheric Pressure (kPa) .....:	540hPa to 1060hPa	-
5.5	**a) Supply voltage during tests was the least favourable of the voltages specified in 4.10.2 or voltages marked on me equipment (V)** .....:	Rated: 100-240 Vac or 100-120Vac (TP/TP3 models with NA standard plug), Tested: 85Vac, 90 Vac, and 264 Vac	Pass
	b) Me equipment marked with a rated frequency range tested at the least favourable frequency within the range (Hz).....:	Rated: 50-60 Hz, Tested: 50 Hz and 60 Hz	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	c) Me equipment with more than one rated voltage, both a.c./ d.c. or both external power and internal electrical power source tested in conditions (see 5.4) related to the least favourable voltage, nature of supply, and type of current .....:		N/A
	d) Me equipment intended for only d.c. supply connection tested with d.c. and influence of polarity considered .....:		N/A
	e)Me equipment tested with alternative accessories and components specified in accompanying documents to result in the least favourable conditions .....:		N/A
	f) Me equipment connected to a separate power supply as specified in instructions for use		N/A
5.7	**Me equipment or parts thereof affected by climatic conditions were set up completely, or partially, with covers detached and subjected to a humidity preconditioning prior to tests of Clauses 8.7.4 and 8.8.3** .....:	See SP Table	Pass
	ME EQUIPMENT heated to a temperature between T and T + 4°C for at least 4 h and placed in a humidity chamber and ambient within 2 °C of T in range of +20°C to +30°C for indicated time	T = 30°C, 93% Time :168h	-
5.9	**Determination of applied parts and accessible parts**		Pass
5.9.1	**Applied parts identified by inspection and reference to accompanying documents** .....:	Component, to be evaluated in end product	N/A
5.9.2	**Accessible parts**		Pass
5.9.2.1	**Accessibility determined using standard test finger of Fig. 6**	See Appended Table 5.9.2	Pass
5.9.2.2	**Test hook of Fig. 7 inserted in all openings of me equipment and pulled with a force of 20 N for 10 s**		Pass
5.9.2.3	**Conductive parts of actuating mechanisms of electrical controls accessible after removal of handles, knobs, levers and the like regarded as accessible parts**.....:	No such parts provided	N/A
	Conductive parts of actuating mechanisms not considered accessible parts when removal of handles, knobs, required use of a tool.....:		N/A
6	**CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS**		Pass
6.2	**Class i me equipment, externally powered**		N/A
	Class ii me equipment, externally powered		Pass
	Internally powered me equipment		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	equipment with means of connection to a supply mains complied with class i or class ii me equipment requirements when so connected, and when not connected to supply mains with internally powered me equipment requirements		N/A
	Type b applied part		N/A
	Type bf applied part		N/A
	Type cf applied part		N/A
	Defibrillation-proof applied parts		N/A
6.3	**Enclosures classified according to degree of protection against ingress of water and particulate matter as per IEC 60529**.....:	IP22	Pass
6.4	**Me equipment or its parts intended to be sterilized classified according to method(s) of sterilization in instructions for use**.....:	No parts intended to be sterilized	N/A
6.5	**Me equipment and me systems intended for use in an oxygen rich environment classified for such use and complied with 11.2.2**		N/A
6.6	**Continuous or Non-continuous operation**.....:	Continuous	Pass
7	**ME EQUIPMENT IDENTIFICATION, MARKING, AND DOCUMENTS**		Pass
7.1.2	**Legibility of Markings Test for Markings specified in Clause 7.2-7.6**.....:	See Appended Table 7.1.2	Pass
7.1.3	**Required markings can be removed only with a tool or by appreciable force, are durable and remain clearly legible during expected service life of me equipment in normal use**	See appended Tables 7.1.3 and 8.10	Pass
7.2	**Marking on the outside of me equipment or me equipment parts**		Pass
7.2.1	**At least markings in 7.2.2, 7.2.5, 7.2.6, 7.2.10, and 7.2.13 were applied when size of equipment, its part, an accessory, or enclosure did not permit application of all required markings**.....:	See attached copy of Marking Plate	Pass
	Remaining markings fully recorded in accompanying documents .....:	Component, to be evaluated in end product	N/A
	Markings applied to individual packaging when impractical to apply to me equipment		N/A
	Single use item marked .....:	No single use part	N/A
7.2.2	**Me equipment marked with** .....:		Pass
	– the name or trademark and contact information of the manufacturer		Pass
	– a model or type reference	See attached copy of Marking Plate	Pass
	– a serial number or lot or batch identifier; and		Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	– the date of manufacture or use by date	Component, to be evaluated in end product	N/A
	Detachable components of the me equipment not marked; misidentification does not present an unacceptable risk, or		N/A
	risk management file includes an assessment of the risks relating to misidentification of all detachable parts: (ISO 14971 Cl. 5.2-5.5, 6, 7.3)		N/A
	Detachable components of the me equipment are marked with the name or trademark of the manufacturer, and		N/A
	– a model or type reference		N/A
	Software forming part of a pems identified with a unique identifier.....:		N/A
7.2.3	**Symbol 11 on Table D.1 used, optionally, advice to operator to consult accompanying documents**	Component, to be evaluated in end product	N/A
	safety sign 10 on Table D.2) used, advising operator that accompanying documents must be consulted		N/A
7.2.4	**Accessories marked with name or trademark and contact information of their manufacturer, and** .....:	Component, to be evaluated in end product	N/A
	- with a model or type reference		N/A
	– a serial number or lot or batch identifier		N/A
	– the date of manufacture or use by date		N/A
	Markings applied to individual packaging when not practical to apply to accessories		N/A
7.2.5	**Me equipment and Me system intended to receive power from other equipment, provided with one of the following**		N/A
	- the name or trademark of the manufacturer of the other electrical equipment and type reference marked adjacent to the relevant connection point; or		N/A
	– Table D.2, safety sign No. 10 adjacent to the relevant connection point and listing of the required details in the instructions for use; or		N/A
	– Special connector style used that is not commonly available on the market and listing of the required details in the instructions for use.		N/A
7.2.6	**Connection to the Supply Mains**		Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	Marking appearing on the outside of part containing SUPPLY MAINS connection and, adjacent to connection point		Pass
	For permanently installed me equipment, Nominal supply voltage or range marked inside or outside of me equipment		N/A
	– rated supply voltage(s) or rated voltage range(s) with a hyphen (-) between minimum and maximum voltages (V, V-V).....:	100-240V~ or 100-120V~	Pass
	Multiple rated supply voltages or multiple rated supply voltage ranges are separated by (V/V)...:		N/A
	– Nature of supply and type of current .....:	Single-phase	Pass
	Symbols 1-5, Table D.1 (used for same parameters .....:	Marked with "~"	Pass
	– rated supply frequency or rated frequency range in hertz .....:	50-60Hz	Pass
	– Symbol 9 of Table D.1 used for class ii me equipment.....:	Has been marked on the Class II (F1 insulation construction) only	Pass
7.2.7	**Rated input in amps or volt-amps, (A, VA)** .....:	A	Pass
	Rated input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A, VA, W) .....:		N/A
	Rated input for one or more rated voltage ranges provided for upper and lower limits of the range or ranges when the range(s) is/are greater than ± 10 % of the mean value of specified range (A, VA,W).....:	See marking label	Pass
	Input at mean value of range marked when range limits do not differ by more than 10 % from mean value (A, VA, W).....:		N/A
	Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in accompanying documents (VA).....:		N/A
	Marked input of me equipment provided with means for connection of supply conductors of other electrical equipment includes rated and marked output of such means (A, VA, W).....:		N/A
7.2.8	**Output connectors**		Pass
7.2.8.2	**Output connectors are marked, except for multiple socket-outlets or connectors intended for specified accessories or equipment**		Pass
	Rated Voltage (V), Rated Current (A).....:	See attached copy of Marking Plate	-
	Rated Power (W), Output Frequency (Hz) .....:	See attached copy of Marking Plate	-

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Clause	Requirement + Test	Result - Remark	Verdict
7.2.9	**Me equipment or its parts marked with the IP environmental Code per IEC 60529 according to classification in 6.3 (Table D.3, Code 2), marking optional for me equipment or parts rated IPX0** .....:	IP22	Pass
7.2.10	**Degrees of protection against electric shock as classified in 6.2 for all applied parts marked with relevant symbols** .....:	Component, to be evaluated in end product	N/A
	Type b applied parts with symbol 19 of Table D.1 .....:		N/A
	Type bf applied parts with symbol 20 of Table D.1 .....:		N/A
	Type cf applied parts with symbol 21 of Table D.1 .....:		N/A
	Defibrillation-proof applied parts marked with symbols 25-27 of Table D.1 .....:		N/A
	Proper symbol marked adjacent to or on connector for applied part .....:		N/A
	safety sign 2 of Table D.2 placed near relevant outlet .....:		N/A
	An explanation indicating protection of me equipment against effects of discharge of a cardiac defibrillator depends on use of proper cables included in instructions for use.....:		N/A
7.2.11	**Me equipment suitable for continuous operation**		Pass
	Duty cycle for me equipment intended for non-continuous operation appropriately marked to provide maximum "on" and "off" time.....:		N/A
7.2.12	**Type and full rating of a fuse marked adjacent to accessible fuse-holder**	No accessible fuse-holder provided	N/A
	Fuse type .....:		-
	Voltage (V) and Current (A) rating .....:		-
	Operating speed (s) and Breaking capacity .....:		-
7.2.13	**Physiological effects – safety sign and warning statements** .....:	No parts can produce physiological effects	N/A
	Nature of hazard and precautions for avoiding or minimizing the associated risk described in instructions for use: **(ISO 14971 Cl. 5.2-5.5, 6, 7.2)**		N/A
7.2.14	**High voltage terminal devices on the outside of me equipment accessible without the use of a tool marked with symbol 24 of Table D.1**		N/A
7.2.15	**Requirements for cooling provisions marked**...:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
7.2.17	**Packaging marked with special handling instructions for transport and/or storage** .....:	To be evaluated in end product	N/A
	Permissible environmental conditions marked on outside of packaging .....:		N/A
	Packaging marked with a suitable safety sign indicating premature unpacking of me equipment could result in an unacceptable risk .....:		N/A
	risk management file includes the assessment to determine premature unpacking of me equipment or its parts could result in an unacceptable risk: **(ISO 14971 Cl. 5.2-5.5, 6, 7.2)**		N/A
	Packaging of sterile me equipment or accessories marked sterile and indicates the methods of sterilization		N/A
7.2.18	**Rated maximum supply pressure from an external source marked on me equipment adjacent to each input connector, and**.....:	No pressure used	N/A
	- the rated flow rate also marked		N/A
7.2.19	**Symbol 7 of Table D.1 marked on functional earth terminal** .....:	Symbol 7 of Table D.1 used. Symbol of IEC 60417-6092 is also used.	Pass
7.2.20	**Removable protective means marked to indicate the necessity for replacement when the function is no longer needed** .....:	Components, to be determined in the end-product	N/A
7.2.21	**mobile me equipment marked with its mass including its safe working load in kilograms**.....:	No mobile equipment	N/A
7.3	**Marking on the inside of me equipment or me equipment parts**		Pass
7.3.1	**Maximum power loading of heating elements or lamp-holders designed for use with heating lamps marked near or in the heater (W)**.....:	No heating elements	N/A
	A marking referring to accompanying documents provided for heating elements or lamp-holders designed for heating lamps that can be changed only by service personnel using a tool		N/A
7.3.2	**Symbol 24 of Table D.1, or safety sign No.3 of Table D.2 used to mark presence of high voltage parts** .....:	No such parts provided	N/A
7.3.3	**Type of battery and mode of insertion marked** .:	No battery provided	N/A
	An identifying marking provided referring to instructions in accompanying documents for batteries intended to be changed only by service personnel using a tool.....:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	A warning provided indicating replacement of lithium batteries or fuel cells when incorrect replacement would result in an unacceptable risk .....:		N/A
	risk management file includes an assessment to determine the replacement of lithium batteries or fuel cells leads to an hazardous situation if replaced incorrectly: (ISO 14971 Cl. 5.2-5.5, 6, 7.2)		N/A
	accompanying documents contain a warning indicating the replacement of lithium batteries or fuel cells by inadequately trained personnel could result in a hazardous situation.....:		N/A
7.3.4	**Fuses, replaceable thermal cut-outs and over-current releases, accessible by use of a tool Identified**.....:	Specification adjacent to component	Pass
	Voltage (V) and Current (A) rating.	Current rated T3.15AL, 250Vac	-
	Operating speed(s), size & breaking capacity...:	T,L, Minimum Interrupting rating 50(A)	-
7.3.5	**Protective earth terminal marked with symbol 6 of Table D.1**		N/A
	Markings on or adjacent to protective earth terminals not applied to parts requiring removal to make the connection, and remained visible after connection made		N/A
7.3.6	**Symbol 7 of Table D.1 marked on functional earth terminals**		Pass
7.3.7	**Terminals for supply conductors marked adjacent to terminals**.....:	No such parts provided	N/A
	Terminal markings included in accompanying documents when me equipment too small to accommodate markings		N/A
	Terminals exclusively for neutral supply conductor in permanently installed me equipment marked with Code 1 of Table D.3		N/A
	Marking for connection to a 3-phase supply, complies with IEC 60445		N/A
	Markings on or adjacent to electrical connection points not applied to parts requiring removal to make connection, and remained visible after connection made		N/A
7.3.8	**“For supply connections, use wiring materials suitable for at least X °C” or equivalent, marked at the point of supply connections**		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Statement not applied to parts requiring removal to make the connection, and clearly legible after connections made		N/A
7.4	**Marking of controls and instruments**		N/A
7.4.1	**The "on" & "off" positions of switch to control power to me equipment, including mains switch, marked with symbols 12 and 13 of Table D.1 or**		N/A
	– indicated by an adjacent indicator light, or		N/A
	– indicated by other unambiguous means		N/A
	The "on" & "off" positions of switch to control power to parts of me equipment, marked with symbols 12 and 13 of Table D.1 or		N/A
	- marked with symbols 16 and 17 of Table D.1 or		N/A
	– indicated by an adjacent indicator light, or		N/A
	– indicated by other unambiguous means		N/A
	Switches that brings ME EQUIPMENT into "stand-by" may be indicated by symbol 29 of Table D.1		N/A
	The "on/off" positions of push button switch with bi-stable positions marked with symbol 14 of Table D.1, and		N/A
	– status indicated by adjacent indicator light		N/A
	– status indicated by other unambiguous means		N/A
	The "on/off" positions of push button switch with momentary on position marked with symbol 15 of Table D.1 or		N/A
	– status indicated by adjacent indicator light		N/A
	– status indicated by other unambiguous means		N/A
7.4.2	**Different positions of control devices/switches indicated by figures, letters, or other visual means**		N/A
	risk management file identifies controls where a change in setting during normal use results in an unacceptable risk: (ISO 14971 Cl. 5.2-5.5, 6, 7.1, 7.2)		N/A
	Controls provided with an associated indicating device when change of setting of a control could result in an unacceptable risk to patient in normal use .....:		N/A
	– or an indication of direction in which magnitude of the function changes		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
7.4.3	**Numeric indications of parameters on me equipment expressed in SI units according to ISO 80000-1 except the base quantities listed in Table 1 expressed in the indicated units**		N/A
	ISO 80000-1 applied for application of SI units, their multiples, and certain other units		N/A
	All Markings in Sub-clause 7.4 complied with tests and criteria of 7.1.2 and 7.1.3 .....:		N/A
7.5	**safety signs**		N/A
	safety sign with established meaning used	Component, to be evaluated in end product	N/A
	risk management process identifies markings used to convey a warning, prohibition or mandatory action that mitigate a risk not obvious to the operator: (ISO 14971 Cl. 5.2-5.5, 6, 7.2)		N/A
	Affirmative statement together with safety sign placed in instructions for use if insufficient space on me equipment		N/A
	Specified colours in ISO 3864-1 used for safety signs .....:		N/A
	Safety notices include appropriate precautions or instructions on how to reduce risk(s)		N/A
	safety signs including any supplementary text or symbols described in instructions for use		N/A
	- and in a language acceptable to the intended operator		N/A
7.6	**Symbols**		N/A
7.6.1	**Meanings of symbols used for marking described in instructions for use**.....:	Component, to be evaluated in end product	N/A
7.6.3	**Symbols used for controls and performance conform to the IEC or ISO publication where symbols are defined, as applicable**		N/A
7.7	**Colours of the insulation of conductors**		Pass
7.7.1	**Protective earth conductor identified by green and yellow insulation**		N/A
7.7.2	**Insulation on conductors inside me equipment forming protective earth connections identified by green and yellow at least at terminations**		N/A
7.7.3	**Green and yellow insulation identify only following conductors** .....:	Used in functional earth conductors	Pass
	– protective earth conductors		N/A
	– conductors specified in 7.7.2		N/A
	– potential equalization conductors		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

	– functional earth conductors		Pass
7.7.4	**Neutral conductors of power supply cords are "light blue"**		Pass
7.7.5	**Colours of conductors in power supply cords in accordance with IEC 60227-1 or IEC 60245-1**		Pass
7.8	**Indicator lights and controls**		Pass
7.8.1	**Red indicator lights, not flashing used only for Warning**		N/A
	Yellow indicator lights, not flashing used only for Caution		N/A
	Green indicator lights used only for Ready for use		Pass
	Red flashing used only for high priority alarm condition, interruption of current workflow needed		N/A
	Yellow flashing used only medium priority alarm condition, re-planning of workflow needed		N/A
	Yellow or Cyan, not flashing used for low priority alarm condition, planning of future workflow needed.		N/A
	Other colours: Meaning other than red, yellow, cyan or green (colour, meaning).....:		N/A
7.8.2	**Red used only for emergency control**		N/A
7.9	**Accompanying documents**		N/A
7.9.1	**Me equipment accompanied by documents containing instructions for use, and a technical description**	Component, to be evaluated in end product	N/A
	Accompanying documents identify me equipment by the following, as applicable .....:		N/A
	– Name or trade-name of manufacturer and contact information for the responsible organization can be referred to.....:		N/A
	– model or type reference.....:		N/A
	When accompanying documents provided electronically, usability engineering process includes instructions as to what is required in hard copy or as markings on me equipment		N/A
	Accompanying documents specify special skills, training, and knowledge required of operator or responsible organization and environmental restrictions on locations of use		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

	Accompanying documents written at a level consistent with education, training, and other needs of individuals for whom they are intended		N/A
7.9.2	**Instructions for use include the required information**		N/A
7.9.2.1	**– use of me equipment as intended by the manufacturer**.....:	Component, to be evaluated in end product	N/A
	– frequently used functions,		N/A
	– known contraindication(s) to use of ME EQUIPMENT		N/A
	- parts of the me equipment that are not serviced or maintained while in use with the patient		N/A
	– name or trademark and address of the manufacturer		N/A
	– model or type reference		N/A
	Instruction for use included the following when the patient is an intended operator .....:		N/A
	– the patient is an intended operator		N/A
	– warning against servicing and maintenance while the me equipment is in use		N/A
	- functions the patient can safely use and, where applicable, which functions the patient cannot safely use; and		N/A
	–maintenance the patient can perform		N/A
	Classifications as in Clause 6, all markings per Clause 7.2, and explanation of safety signs and symbols marked on me equipment		N/A
	Instructions for use are in a language acceptable to the intended operator		N/A
7.9.2.2	**Instructions for use include all warning and safety notices**		N/A
	Warning statement for class i me equipment included		N/A
	Warnings regarding significant risks of reciprocal interference posed by me equipment during specific investigations or treatments		N/A
	Information on potential electromagnetic or other interference and advice on how to avoid or minimize such interference		N/A
	Warning statement for me equipment supplied with an integral multiple socket-outlet provided		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	The responsible organization is referred to this standard for the requirements applicable to me systems		N/A
7.9.2.3	**Statement on me equipment for connection to a separate power supply provided in instructions**		N/A
7.9.2.4	**Warning statement for mains- operated me equipment with additional power source not automatically maintained in a fully usable condition indicating the necessity for periodic checking or replacement of power source**		N/A
	risk management file assesses the risk resulting from leakage of batteries: (ISO 14971 Cl. 5.2-5.5, 6, 7.2)		N/A
	Where the risk is unacceptable, the ifu includes a warning to remove the battery if the me equipment is not likely to be used for some time .....:		N/A
	Specifications of replaceable internal electrical power source when provided.....:		N/A
	Warning indicating me equipment must be connected to an appropriate power source when loss of power source would result in an unacceptable risk .....:		N/A
7.9.2.5	**Instructions for use include a description of me equipment, its functions, significant physical and performance characteristics together with the expected positions of operator, patient, or other persons near me equipment in normal use**		N/A
	Information provided on materials and ingredients patient or operator is exposed to		N/A
	Restrictions specified on other equipment or network/data couplings, other than those forming part of an me system, to which a signal input/output part may be connected		N/A
	Applied parts specified		N/A
7.9.2.6	**Information provided indicating where the installation instructions may be found or information on qualified personnel who can perform the installation**		N/A
7.9.2.7	**Instructions provided indicating not to position me equipment to make it difficult to operate the disconnection device**		N/A
7.9.2.8	**Necessary information provided for operator to bring me equipment into operation**		N/A
7.9.2.9	**Information provided to operate me equipment**		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Meanings of figures, symbols, warning statements, abbreviations and indicator lights described in instructions for use		N/A
7.9.2.10	**A list of all system messages, error messages, and fault messages provided with an explanation of messages including important causes and possible action(s) to be taken to resolve the problem indicated by the message**		N/A
7.9.2.11	**Information provided for the operator to safely terminate operation of me equipment**		N/A
7.9.2.12	**Information provided on cleaning, disinfection, and sterilization methods, and applicable parameters that can be tolerated by me equipment parts or accessories specified**		N/A
	Components, accessories or me equipment marked for single use, except when required by manufacturer to be cleaned, disinfected, or sterilized prior to use		N/A
7.9.2.13	**Instructions provided on preventive inspection, calibration, maintenance and its frequency**		N/A
	Information provided for safe performance of routine maintenance necessary to ensure continued safe use of me equipment		N/A
	Parts requiring preventive inspection and maintenance to be performed by service personnel identified including periods of application		N/A
	Instructions provided to ensure adequate maintenance of me equipment containing rechargeable batteries to be maintained by anyone other than service personnel		N/A
7.9.2.14	**A list of accessories, detachable parts, and materials for use with me equipment provided**		N/A
	Other equipment providing power to me system sufficiently described		N/A
7.9.2.15	**Disposal of waste products, residues, etc., and of me equipment and accessories at the end of their expected service life are identified in the instruction for us** .....:		N/A
7.9.2.16	**Instructions for use include information specified in 7.9.3 or identify where it can be found (e.g. in a service manual)**		N/A
7.9.2.17	**Instruction for use for me equipment emitting radiation for medical purposes, indicate the nature, type, intensity and distribution of this radiation**		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
7.9.2.18	**The instructions for use for me equipment or accessories supplied sterile indicate that they have been sterilized and the method of sterilization**		N/A
	The instructions for use indicate the necessary instructions in the event of damage to the sterile packaging, and where appropriate, details of the appropriate methods of re-sterilization		N/A
7.9.2.19	**The instructions for use contain a unique version identifier**.....:		N/A
7.9.3	**Technical description**		N/A
7.9.3.1	**All essential data provided for safe operation, transport, storage, and measures or conditions necessary for installing me equipment, and preparing it for use including**	Component, to be evaluated in end product	N/A
	-information required in 7.2		N/A
	-permissible environmental conditions of use including conditions for transport and storage.. .....:		N/A
	-characteristics of the ME EQUIPMENT, including range(s), accuracy, and precision of the displayed values or an indication where they can be found		N/A
	-special installation requirements such as the maximum permissible apparent impedance of SUPPLY MAINS		N/A
	-permissible range of values of inlet pressure and flow, and the chemical composition of cooling liquid		N/A
	-description of the means for checking the oil level in partially sealed oil filled ME EQUIPMENT or its parts		N/A
	-warning statement that addresses the HAZARDS that can result from unauthorized modification of the ME EQUIPMENT		N/A
	-information pertaining to ESSENTIAL PERFORMANCE and any necessary recurrent ESSENTIAL PERFORMANCE and BASIC SAFETY testing including details of the means, methods and recommended frequency		N/A
	Technical description separable from instructions for use contains required information, as follows		N/A
	-information required by 7.2		N/A
	–applicable classifications in Clause 6, warning and safety notices, and explanation of safety signs marked on me equipment		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

	– brief description of the me equipment, how the me equipment functions and its significant physical and performance characteristics; and		N/A
	a unique version identifier.....:		N/A
	Manufacturer's optional requirements for minimum qualifications of service personnel documented in technical description		N/A
7.9.3.2	**The technical description contains the following required information**		N/A
	–type and full rating of fuses used in supply mains external to permanently installed me equipment.....:	Component, to be evaluated in end product	N/A
	– a statement for me equipment with a non-detachable power supply cord if power supply cord is replaceable by service personnel, and		N/A
	– instructions for correct replacement of interchangeable or detachable parts specified by manufacturer as replaceable by service personnel, and		N/A
	risk management file includes an assessment to determine if replacement of components results in any unacceptable risks: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)		N/A
	– warnings identifying nature of hazard when replacement of a component could result in an unacceptable risk, and when replaceable by service personnel all information necessary to safely replace the component		N/A
7.9.3.3	**Technical description indicates, manufacturer will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to service personnel in parts repair**		N/A
7.9.3.4	**Means used to comply with requirements of 8.11.1 clearly identified in technical description**	Component, to be evaluated in end product	N/A
8	**PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT**		Pass
8.1	**Limits specified in Clause 8.4 not exceeded for accessible parts and applied parts in normal or single fault conditions**		Pass
	risk management file identifies conductors and connectors where breaking free results in a hazardous situation:(ISO 14971 Cl. 5.4)	RMF Reference to specific risks: doc. No. GT-RM2013-010, version A.2, chapter 6.3, Hazard ID 3 (ISO 14971 Cl. 5.4).	Pass
8.2	**Requirements related to power sources**		N/A
8.2.1	**Connection to a separate power source**		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	When me equipment specified for connection to a separate power source other than supply mains, separate power source considered as part of me equipment or combination considered as an me system	Intended to be connected to SUPPLY MAINS	N/A
	Tests performed with me equipment connected to separate power supply when one specified		N/A
	When a generic separate power supply specified, specification in accompanying documents examined		N/A
8.2.2	**Connection to an external d.c. power source**		N/A
	No hazardous situation as described in 13.1 developed when a connection with wrong polarity made for me equipment from an external d.c. source		N/A
	Me equipment connected with correct polarity maintained basic safety and essential performance		N/A
	Protective devices that can be reset by anyone without a tool returns to normal condition on reset		N/A
8.3	**Classification of applied parts**		N/A
	a) Applied part specified in accompanying documents as suitable for direct cardiac application is type cf	No applied parts provided	N/A
	b) An applied part provided with a patient connection intended to deliver electrical energy or an electrophysiological signal to or from patient is type bf or cf applied part		N/A
	c) An applied part not covered by a) or b) is a type b, bf, or cf		N/A
8.4	**Limitation of voltage, current or energy**		Pass
8.4.2	**accessible parts and applied parts**		Pass
	a) Currents from, to, or between patient connections did not exceed limits for patient leakage current & patient auxiliary current .....:	No applied parts provided	N/A
	b) Leakage currents from, to, or between accessible parts did not exceed limits for touch current .....:	See appended Table 8.7	Pass
	c) Limits specified in b) not applied to parts when probability of a connection to a patient, directly or through body of operator, is negligible in normal use, and the operator is appropriately instructed		Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	Voltage to earth or to other accessible parts did not exceed 42.4 V peak a.c. or 60 V d.c. for above parts in normal or single fault condition (V a.c. or d.c.) .....:	See appended Table 8.4.2	Pass
	Energy did not exceed 240 VA for longer than 60 s or stored energy available did not exceed 20 J at a potential of 2 V or more (VA or J) .....:	See appended Table 8.4.2	Pass
	Limits in b) does not apply to sip/sop connectors and separate power supply connectors if the voltage measured is less than or equal to 60 V d.c. or 42,4 V peak a.c		N/A
	d) Voltage and energy limits specified in c) above also applied to the following.....:	No such parts provided	N/A
	– internal parts touchable by test pin in Fig 8 inserted through an opening in an enclosure; and		N/A
	– internal parts touchable by a metal test rod with a diameter of 4 mm and a length 100 mm, inserted through any opening on top of enclosure or through any opening provided for adjustment of pre-set controls by responsible organization in normal use using a tool		N/A
	Test pin or the test rod inserted through relevant openings with minimal force of no more than 1 N		N/A
	Test rod inserted in every possible position through openings provided for adjustment of pre-set controls that can be adjusted in normal use, with a force of 10 N		N/A
	Test repeated with a tool specified in instructions for use		N/A
	Test rod freely and vertically suspended through openings on top of enclosure		N/A
	e) Devices used to de-energize parts when an access cover opened without a tool gives access to parts at voltages above levels permitted by this Clause comply with 8.11.1 for mains isolating switches and remain effective in single fault condition		N/A
	A tool is required when it is possible to prevent the devices from operating		N/A
8.4.3	**Worst case voltage between pins of plug and between either supply pin and enclosure did not exceed 60 V one sec after disconnecting the plug of me equipment or its parts (V)** .....:	See appended Table 8.4.3	Pass
	When voltage exceeded 60 V, calculated or measured stored charge didn't exceed 45µC....:	Voltage less than 60 V	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
8.4.4	**Residual voltage of conductive parts of capacitive circuits, having become accessible after me equipment was de-energized after removal of access covers, didn't exceed 60V or calculated stored charge didn't exceed 45µC** ...:		N/A
	A device manually discharging capacitors used when automatic discharging was not possible and access covers could be removed only with aid of a tool		N/A
	Capacitor(s) and connected circuitry marked with symbol 24 of Table D.1, and manual discharging device specified in technical description .....:		N/A
8.5	**Separation of parts**		Pass
8.5.1	**Means of protection (mop)**		Pass
8.5.1.1	**Two means of protection provided for me equipment to prevent applied and other accessible parts from exceeding limits in 8.4**		Pass
	A means of protection protecting applied parts or parts identified by 4.6 as parts subject to the same requirements, considered as means of patient protection .....:		N/A
	Varnishing, enamelling, oxidation, and similar protective finishes and coatings with sealing compounds re-plasticizing at temperatures expected during operation and sterilization disregarded as means of protection		Pass
	Components and wiring forming a means of protection comply with 8.10		Pass
8.5.1.2	**means of patient protection (MOPP)**		Pass
	Solid insulation forming a means of patient protection complied with dielectric strength test .....:	See appended Table 8.8.3	Pass
	Creepage and clearances forming a means of patient protection complied with Table 12		Pass
	Protective earth connections forming a means of patient protection complied with Cl. 8.6		N/A
	Y1 or Y2 capacitor complying with standard IEC 60384-14 considered one means of patient protection .....:	See appended Tables 8.8.3 and 8.10	Pass
	Single Y1 capacitor used for two means of patient protection when the working voltage is less than 42,4 V peak a.c. or 60 V d.c .....:		N/A
	Two capacitors used in series, each rated for total working voltage across the pair and have the same nominal capacitance	Two Y1 capacitors are series connected between Pri. and Sec. circuit	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	Voltage Total Working (V) and C Nominal (µF)..:	min 250Vac, rated max.2200pF except for F3 construction, rated max.1500pF for F3 construction	-
	Optocouplers complying with IEC 60747-5-5:2007, or a later edition. Considered equivalent to requirements in 8.8.2 and 8.9.3	See table 8.10	Pass
	Measurement of Air Clearance and Creepage distance on the outside	See insulation table	Pass
	Dielectric strength test across optocoupler		N/A
8.5.1.3	**means of operator protection (MOOP)**	MOOP provided between L and N before fuses only.	Pass
	Solid insulation forming a means of operator protection complied with .....:	See below	Pass
	– dielectric strength test .....:	See appended Table 8.8.3	Pass
	– requirements of IEC 60950-1:2005, IEC 60950-1:2005/A1:2009 and IEC 60950:2005/A2:2013 or requirements of IEC 62368-1:2018 for insulation co-ordination		N/A
	Creepage and clearances forming a means of operator protection complied with .....:	See below	Pass
	– limits of Tables 13 to 16 (inclusive); or		Pass
	– requirements of IEC 60950-1:2005, IEC 60950-1:2005/A1:2009 and IEC 60950:2005/A2:2013 or requirements of IEC 62368-1:2018 for INSULATION CO-ORDINATION		N/A
	Protective earth connections forming a means of operator protection complied with Cl. 8.6		N/A
	– or with requirements and tests of IEC 60950-1:2005, IEC 60950-1:2005/A1:2009 and IEC 60950:2005/A2:2013 or requirements of IEC 62368-1:2018 for protective earthing .....:		N/A
	A Y2 (IEC 60384-14) capacitor is considered one means of operator protection .....:		N/A
	A Y1 (IEC 60384-14) capacitor is considered two means of operator protection .....:		N/A
	Two capacitors used in series each rated for total working voltage across the pair and have the same nominal capacitance		N/A
	Voltage Total Working (V) and C Nominal (µF)..:		-
	Optocouplers complying with IEC 60747-5-5:2007, or a later edition. Considered equivalent to requirements in 8.8.2 and 8.9.3		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Measurement of Air Clearance and Creepage distance on the outside		N/A
	Dielectric strength test across optocoupler		N/A
	Points and applied parts at which impedances of components, creepage, clearances, protective earth connections or insulation, prevent accessible parts from exceeding limits in 8.4 were examined whether a failure at any of these points is to be regarded as a normal or single fault condition		N/A
8.5.2	**Separation of patient connections**		N/A
8.5.2.1	**Patient connections of F-type applied part separated from all other parts by equivalent to one means of patient protection for a working voltage equal to the max. mains voltage** .....:	Component, to be evaluated in end product	N/A
	Separation requirement not applied between multiple functions of a single F-type applied part		N/A
	Patient connections treated as one applied part in the absence of electrical separation between patient connections of same or another function		N/A
	Manufacturer has defined if multiple functions are to be considered as all within one applied part or as multiple applied parts .....:		N/A
	Classification as type bf, cf, or defibrillation-proof applied to one entire applied part		N/A
	Leakage current tests conducted per 8.7.4 .....:		N/A
	Dielectric strength test conducted per 8.8.3.....:		N/A
	Creepage and clearances measured .....:		N/A
	A protective device connected between patient connections of an F-type applied part and enclosure to protect against excessive voltages did not operate below 500 V r.m.s		N/A
8.5.2.2	**Patient connections of a type b applied part not protectively earthed are separated by one means of patient protection from metal accessible parts not protectively earthed**.....:	Component, to be evaluated in end product	N/A
	– except when metal accessible part is physically close to applied part and can be regarded as a part of applied part; and		N/A
	– risk that metal accessible part will make contact with a source of voltage or leakage current above permitted limits is acceptably low. In this case 8.7.4.7 d) does not apply		N/A
	Leakage current tests conducted per 8.7.4 .....:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Dielectric strength test conducted per 8.8.3.....:		N/A
	Relevant creepage and clearances measured		N/A
	risk management file includes an assessment of the risk of metal accessible parts contacting a source of voltage or leakage current above the limits:(ISO 14971 Cl. 5.2-5.5, 6)		N/A
8.5.2.3	**A connector on a patient lead or patient cable located at the end of the lead or cable distal from patient, with conductive part not separated from all patient connections by one means of patient protection for a working voltage equal to maximum mains voltage**		N/A
	- cannot be connected to earth or hazardous voltage while the patient connections are in contact with patient.....:	Component, to be evaluated in end product	N/A
	– conductive part of connector not separated from all patient connections did not come into contact with a flat conductive plate of not less than 100 mm diameter		N/A
	– clearance between connector pins and a flat surface is at least 0.5 mm		N/A
	– conductive part pluggable into a mains socket protected from contacting parts at mains voltage by insulation with a creepage distance of at least 1.0 mm, a 1500 V dielectric strength and complying with 8.8.4.1		N/A
	– required test finger did not make electrical contact with conductive part when applied against access openings with a force of 10 N,		N/A
	Test finger test (10 N).....:		N/A
	Except when risk management process includes an assessment of risks resulting from contact with objects other than mains sockets or flat surfaces: (ISO 14971 Cl. 5.2-5.5, 6)		N/A
8.5.4	**Working voltage**		Pass
	– Input supply voltage to me equipment was rated voltage or voltage within rated range resulting in highest measured value (V) .....:	240V~	Pass
	– Working voltage for d.c. voltages with superimposed ripple was average value when peak-to-peak ripple less than 10% of average value or peak voltage when peak-to-peak ripple exceeding 10% of average value (V).....:		N/A
	– Working voltage for each means of protection forming double insulation was voltage double insulation, as a whole, subjected to (V).....:	See Insulation Diagram and Insulation Table	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	– Intentional or accidental earthing of patient regarded as a normal condition for working voltage involving a patient connection not connected to earth		N/A
	– Working voltage between patient connections of an f-type applied part and enclosure was highest voltage appearing across insulation in normal use including earthing of any part of applied part (V) .....:		N/A
	– Working voltage for defibrillation-proof applied parts determined disregarding possible presence of defibrillation voltages		N/A
	– Working voltage was equal to resonance voltage in case of motors provided with capacitors between the point where a winding and a capacitor are connected together and a terminal for external conductors (V) .....:		N/A
8.5.5	**Defibrillation-proof applied parts**	Component, to be evaluated in end product	N/A
8.5.5.1	**Classification "defibrillation-proof applied part" applied to one applied part in its entirety**		N/A
	Isolation of patient connections of a defibrillation-proof applied part from other parts of me equipment accomplished as follows .....:		N/A
	a) No hazardous electrical energies appear during a discharge of cardiac defibrillator .....:		N/A
	b) Me equipment complied with relevant requirements of this standard, providing basic safety and essential performance following exposure to defibrillation voltage, and recovery time stated in accompanying documents.....:		N/A
8.5.5.2	**Means provided to limit energy delivered to a 100 Ω load** .....:		N/A
8.6	**Protective and functional earthing and potential equalization of me equipment**		Pass
8.6.1	**Requirements of 8.6.2 to 8.6.8 applied**		Pass
	Parts complying with IEC 60950-1:2005, IEC 60950-1:2005/amd1:2009 and IEC 60950-1:2005/amd2:2013 or IEC 62368-1:2018 for protective earthing and serving as means of operator protection but not patient protection exempted from requirements of 8.6.2 to 8.6.8		N/A
8.6.2	**Protective earth terminal is suitable for connection to an external protective earthing system by a protective earth conductor in a power supply cord and a suitable plug or by a fixed protective earth conductor**.....:	No protective earth terminal	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Clamping means of protective earth terminal of me equipment for fixed supply conductors or power supply cords comply with 8.11.4.3, and cannot be loosened without tool		N/A
	Screws for internal protective earth connections completely covered or protected against accidental loosening from outside .....:		N/A
	Earth pin of appliance inlet forming supply connection to me equipment regarded as protective earth terminal		N/A
	Protective earth terminal not used for mechanical connection between different parts of me equipment or securing components not related to protective or functional earthing		N/A
8.6.3	**Protective earth connection not used for a moving part,**		N/A
	except when manufacturer demonstrated in risk management file connection will remain reliable during expected service life : (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)		N/A
8.6.4	**a) Protective earth connections carried fault currents reliably and without excessive voltage drop**.....:		N/A
	b) Allowable touch current and patient leakage current in single fault condition were not exceeded, when impedance of protective earth connections exceeded values in 8.6.4 a) and Table 8.6.4, due to limited current capability of relevant circuits .....:		N/A
	Detachable power supply cord specified by manufacturer or delivered with product		N/A
8.6.5	**Surface coatings**		N/A
	Poorly conducting surface coatings on conductive elements removed at the point of contact		N/A
	Coating not removed when requirements for impedance and current-carrying capacity met		N/A
8.6.6	**Plugs and sockets**		N/A
	Protective earth connection where connection between supply mains and me equipment or between separate parts of me equipment made via a plug and socket was made before and interrupted after supply connections		N/A
	- applied also where interchangeable parts are protectively earthed		N/A
8.6.7	**Terminal for connection of a potential equalization conductor**		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– Terminal is accessible to operator with me equipment in any position of normal use		N/A
	–accidental disconnection avoided in normal use		N/A
	– Terminal allows conductor to be detached without a tool		N/A
	– Terminal not used for a protective earth connection		N/A
	– Terminal marked with symbol 8 of Table D.1		N/A
	– Instructions for use contain information on function and use of potential equalization conductor together with a reference to requirements of this standard		N/A
	Power supply cord does not incorporate a potential equalization conductor		N/A
8.6.8	**Functional earth terminal not used to provide a protective earth connection**		Pass
8.6.9	**Class II me equipment**		Pass
	Third conductor of power supply cord connected to protective earth contact of mains plug provided with class ii me equipment with isolated internal screens used as functional earth connection to the screen's functional earth terminal, coloured green and yellow		Pass
	accompanying documents include a statement that the third conductor in the power supply cord is only a functional earth.	Component, to be evaluated in end product	N/A
	Two means of protection provided between insulation of internal screens and all internal wiring connected to them and accessible parts		Pass
8.7	**Leakage currents and patient auxiliary currents**		Pass
8.7.1	**a) Electrical isolation providing protection against electric shock limits currents to values in 8.7.3**.....:	See appended Tables 8.7	Pass
	b) Specified values of earth leakage, touch, patient leakage, and patient auxiliary currents applied in combination of conditions in appended Table 8.7 .....:	See appended Tables 8.7	Pass
8.7.2	**Allowable values specified in 8.7.3 applied under single fault conditions of 8.1 b), except**		Pass
	– where insulation used in conjunction with a protective earth connection, insulation short circuited only under conditions in 8.6.4 b)		N/A
	– the only single fault condition for earth leakage current was interruption of one supply conductor at a time		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– leakage currents and patient auxiliary current not measured in single fault condition of short circuiting of one constituent part of double insulation		Pass
	Single fault conditions not applied at same time as special test conditions of maximum mains voltage on applied parts and non-protectively earthed parts of enclosure		Pass
8.7.3	**Allowable Values**		Pass
	a) Allowable values in 8.7.3 b), c), and d) measured based on, and are relative to currents in Fig 12 a), or by a device measuring frequency contents of currents as in Fig 12 b...:	See appended Table 8.7	Pass
	b) Allowable values of patient leakage and auxiliary currents are according to Tables 3 & 4, and values of a.c. are relative to currents having a frequency not less than 0.1Hz .....:	No applied parts provided	N/A
	c) Touch current did not exceed 100µA in normal condition and 500µA in single fault condition (ITNC, ITSFC) .....:	See appended Table 8.7	Pass
	d) Earth leakage current did not exceed 5 mA in normal condition and 10 mA in single fault condition (IENC, IESFC) .....:		Pass
	Higher values of earth leakage current permitted for permanently installed me equipment connected to a supply circuit supplying only this me equipment according to local regulations or IEC 60364-7-710 .....:		N/A
	e) Leakage currents, regardless of waveform and frequency, did not exceed 10 mA r.m.s. in normal or in single fault condition (measured with a non-frequency-weighted device .....:	See appended Table 8.7	Pass
	f) leakage currents flowing in a functional earth conductor in a non-permanently installed me equipment are 5 mA in normal condition, 10 mA in single fault condition .....:	See appended Table 8.7	Pass
8.7.4	**leakage and patient auxiliary currents measurements** .....:	See appended Table 8.7	Pass
8.8	**Insulation**		Pass
8.8.1	**Insulation relied on as means of protection, including reinforced insulation subjected to testing**		Pass
	Insulation exempted from test (complies with clause 4.8)		N/A
	Insulation forming means of operator protection and complying with IEC 60950-1 for insulation co-ordination not tested as in 8.8		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

8.8.2	**Distance through solid insulation or use of thin sheet material**		Pass
	Solid insulation forming supplementary or reinforced insulation for a peak working voltage greater than 71 V provided with .....:	See below	Pass
	a) 0.4 mm, min, distance through insulation, or	Plastic enclosure	Pass
	b) does not form part of an enclosure and not subject to handling or abrasion during normal use, and comprised of .....:	See appended Table 8.8.3	Pass
	– at least two layers of material, each passed the appropriate dielectric strength test.....:	Two layers of Insulation tapes provided on HS1, see appended Table 8.8.3	Pass
	– or three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength test.....:		N/A
	Dielectric strength test for one or two layers was same as for one means of protection for supplementary insulation		Pass
	Dielectric strength test for one or two layers was same as for two means of protection for reinforced insulation		N/A
	basic, supplementary, and reinforced insulation required between windings of wound components separated by interleaved insulation complying with a) or b), or both, except when		N/A
	c) Wire with solid insulation, other than solvent based enamel, complying with a)		N/A
	d) Wire with multi-layer extruded or spirally wrapped insulation complying with b) and complying with Annex L		N/A
	e) Finished wire with spirally wrapped or multi-layer extruded insulation, complying with Annex L		Pass
	– basic insulation: minimum two wrapped layers or one extruded layer		N/A
	– supplementary insulation: minimum two layers, wrapped or extruded		N/A
	– reinforced insulation: minimum three layers, wrapped or extruded	UL recognized TIW with VDE certificate.	Pass
	In d) and e), for spirally wrapped insulation with creepage distances between layers less than in Table 12 or 16 (Pollution Degree 1) depending on type of insulation, path between layers sealed as a cemented joint in 8.9.3.3 and test voltages of type tests in L.3 equal 1.6 times of normal values		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Protection against mechanical stress provided where two insulated wires or one bare and one insulated wire are in contact inside wound component, crossing at an angle between 45° and 90° and subject to winding tension.....:		Pass
	Finished component complied with routine dielectric strength tests of 8.8.3.....:	See appended Table 8.8.3	Pass
	Tests of Annex L not repeated since material data sheets confirm compliance.....:	See Table 8.10	Pass
8.8.3	**Dielectric Strength**		Pass
	Solid insulating materials with a safety function withstood dielectric strength test voltages .....:	See appended Table 8.8.3	Pass
8.8.4	**Insulation other than wire insulation**		Pass
8.8.4.1	**Resistance to heat retained by all insulation and insulating partition walls during expected service life of me equipment**		Pass
	Me equipment and design documentation examined .....:	Test conducted	N/A
	risk management file examined in conjunction with resistance to moisture, dielectric strength, and mechanical strength tests: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)		N/A
	Satisfactory evidence of compliance provided by manufacturer for resistance to heat.....:		N/A
	Tests conducted in absence of satisfactory evidence for resistance to heat.....:	See appended Table 8.8.4.1	Pass
	a) Enclosure and other external parts of insulating material, except insulation of flexible cords and parts of ceramic material, subjected to ball-pressure test using Fig 21 apparatus.....:	See appended Table 8.8.4.1	Pass
	b) Parts of insulating material supporting uninsulated parts of mains part subjected to ball-pressure test in a), except at 125 °C ± 2 ° C or ambient indicated in technical description ±2°C plus temperature rise determined during test of 11.1 of relevant part, if higher (°C) .....:		N/A
	Test not performed on parts of ceramic material, insulating parts of commutators, brush-caps, and similar, and on coil formers not used as reinforced insulation		N/A
8.8.4.2	**Resistance to environmental stress**		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Insulating characteristics and mechanical strength of all means of protection not likely to be impaired by environmental stresses including deposition of dirt resulting from wear of parts within equipment, potentially reducing creepage and clearances below 8.9	Component, to be evaluated in end product	N/A
	Ceramic and similar materials not tightly sintered, and beads alone not used as supplementary or reinforced insulation		N/A
	Insulating material with embedded heating conductors considered as one means of protection but not two means of protection		N/A
	Parts of natural latex rubber aged by suspending samples freely in an oxygen cylinder containing commercial oxygen to a pressure of 2.1 MPa ± 70 kPa, with an effective capacity of at least 10 times volume of samples		N/A
	There were no cracks visible to naked eyes after samples kept in cylinder at 70 °C ± 2 °C for 96h, and afterwards, left at room temperature for at least 16h		N/A
8.9	**Creepage distances and air clearances**		Pass
8.9.1.1	**Creepage distances and air clearances are equal to or greater than values in Tables 12 to 16 (inclusive)**.....:	Refer to Insulation Diagram	Pass
8.9.1.15	**Creepage distances and air clearances for defibrillation-proof applied parts are 4 mm or more to meet 8.5.5.1**		N/A
8.9.1.16	**Conductive coatings applied to non-metallic surfaces, do not result in flaking or peeling reducing any air clearance or creepage distance**		N/A
8.9.2	**a) Short circuiting of each single one of creepage distances and clearances in turn did not result in a hazardous situation , min creepage and clearances not applied** .....:	See appended Table 13.2	Pass
8.9.3	**Spaces filled by insulating compound**		N/A
8.9.3.1	**Only solid insulation requirements applied where distances between conductive parts filled with insulating compound**		N/A
	Thermal cycling, humidity preconditioning, and dielectric strength tests		N/A
8.9.3.2	**For insulating compound forming solid insulation between conductive parts, a single sample subjected to thermal cycling procedure of 8.9.3.4 followed by humidity preconditioning per 5.7 (for 48 hours), followed by dielectric strength test (cl. 8.8.3 at 1,6 x test voltage)**.....:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Cracks or voids in insulating compound affecting homogeneity of material didn't occur		N/A
8.9.3.3	**Where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint**		N/A
	A winding of solvent-based enamelled wire replaced for the test by a metal foil or by a few turns of bare wire placed close to cemented joint, and three samples tested as follows .....:		N/A
	– One sample subjected to thermal cycling procedure of 8.9.3.4, and immediately after the last period at highest temperature during thermal cycling followed by dielectric strength test of cl. 8.8.3 at 1.6 x the test voltage .....:		N/A
	– The other two samples subjected to humidity preconditioning of 5.7, except for 48 hours only followed by a dielectric strength test of cl. 8.8.3 at 1.6 times the test voltage		N/A
8.9.4	**Minimum spacing of grooves transvers to the creepage distances considered a means of operator protection adjusted based on pollution degree**.....:	Pollution degree: II	Pass
	Force was applied between bare conductors and outside metal enclosure when measuring creepage distances and air clearances		N/A
8.10	**Components and wiring**		Pass
8.10.1	**Components of me equipment likely to result in an unacceptable risk by their movements mounted securely**.....:	Complied by inspection	Pass
	risk management file includes an assessment of risks related to unwanted movement of components: **(ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)**	RMF Reference to specific risks: doc. No. GT-RM2013-010, version A.2, chapter 6.3, Hazard ID 3 (ISO 14971 Cl. 5.2-5.5, 6).	Pass
8.10.2	**Conductors and connectors of me equipment adequately secured or insulated to prevent accidental detachment**.....:	Secured firmly to prevent accidental detachment	Pass
	Stranded conductors are not solder-coated when secured by clamping means to prevent hazardous situations		Pass
8.10.3	**Interconnecting flexible cords detachable without a tool used provided with means for connection to comply with requirements for metal accessible parts when a connection is loosened or broken** .....:	Power output cords cannot be detachable.	N/A
8.10.4	**Cord-connected hand-held parts and cord-connected foot-operated control devices**		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
8.10.4.1	**Control devices of me equipment and their connection cords contain only conductors and components operating at 42.4 V peak a.c., max, or 60 V d.c. in circuits isolated from mains part by two means of protection**		N/A
8.10.4.2	**Connection and anchorage of a flexible cord to a hand-held or foot-operated control device of me equipment, at both ends of the cable to the control device, complies with the requirements for power supply cords in Cl. 8.11.3**		N/A
	Other hand-held parts, if disturbance or breaking of one or more of the connections could result in a hazardous situation, also comply with tests of Cl. 8.11.3		N/A
8.10.5	**Mechanical protection of wiring**		Pass
	a) Internal cables and wiring adequately protected against contact with a moving part or from friction at sharp corners and edges .....:	Internal cables and wiring adequately protected against from friction at sharp corners and edges	Pass
	b) Wiring, cord forms, or components are not likely to be damaged during assembly or during opening or closing of access covers		Pass
8.10.6	**Guiding rollers prevent bending of movable insulated conductors around a radius of less than five times the outer diameter of the lead**		N/A
8.10.7	**a) Insulating sleeve adequately secured**.....:	See appended Table 8.10	Pass
	b) Sheath of a flexible cord not used as a means of protection inside me equipment when it is subject to mechanical or thermal stresses beyond its rated characteristics		N/A
	c) Insulated conductors of me equipment subject to temperatures exceeding 70 °C .....:		N/A
8.11	**Mains parts, components and layout**		Pass
8.11.1	**a) Me equipment provided with means of electrically isolating its circuits from supply mains simultaneously on all poles** .....:	See appended Table 8.10	Pass
	Permanently installed me equipment connected to a poly-phase supply mains equipped with a device not interrupting neutral conductor, provided local installation conditions prevent voltage on neutral conductor from exceeding limits in 8.4.2 c)		N/A
	permanently installed me equipment provided with means to isolate its circuits electrically from the supply mains are capable of being locked in the off position		N/A
	- the isolation device specified in the accompanying documents		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	b) Means of isolation incorporated in me equipment, or if external, described in technical description.....:	Component, to be evaluated in end product	N/A
	c) A supply mains switch used to comply with 8.11.1 a) complies with creepage / clearances for a mains transient voltage of 4 kV.....:	No such parts provided	N/A
	d) A supply mains switch not incorporated in a power supply cord or external flexible lead		N/A
	e) Actuator of a supply mains switch used to comply with 8.11.1 a) complies with IEC 60447		N/A
	f) A suitable plug device used in non-permanently installed me equipment with no supply mains switch .....:	Component, to be evaluated in end product	N/A
	g) A fuse or a semiconductor device not used as an isolating means		Pass
	h) Me equipment not provided with a device causing disconnection of me equipment from supply mains by producing a short circuit resulting in operation of an overcurrent protection device		Pass
	i) Parts within enclosure of me equipment with a circuit > 42.4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply by an external switch or a plug device accessible at all times is protected against touch even after opening enclosure by an additional covering		N/A
	A clear warning notice is marked on outside of me equipment to indicate it exceeds allowable touch voltage		N/A
	For a part that could not be disconnected from supply by an external switch or a plug device accessible at all times, the required cover or warning notice complied with this clause		N/A
	Standard test finger applied		N/A
8.11.2	**Multiple socket-outlets integral with me equipment complied with 16.2 d), second dash; and 16.9.2**		N/A
8.11.3	**Power supply cords**		Pass
8.11.3.1	**Mains plug not fitted with more than one power supply cord**		Pass
8.11.3.2	**Power supply cords are no less robust than ordinary tough rubber sheathed flexible cord (IEC 60245-1:2003, Annex A, designation 53) or ordinary polyvinyl chloride sheathed flexible cord (IEC 60227-1:1993, Annex A, design 53)**....:	See appended Table 8.10	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	Only polyvinyl chloride insulated power supply cord with appropriate temperature rating used for me equipment having external metal parts with a temperature > 75 °C touchable by the cord in normal use .....:	See appended Table 8.10	Pass
8.11.3.3	**Nominal cross-sectional area of conductors of power supply cords of me equipment is not less than in Table 17** .....:	18AWG power cord used (min 0.75 mm2 in table 17)	Pass
	For me equipment utilizing power supply cords and operating at currents greater than 63 A, apply the electrical regulations appropriate for the jurisdiction in which the me equipment is to be used.		N/A
8.11.3.4	**Appliance couplers complying with IEC 60320-1 are considered to comply with 8.11.3.5 and 8.11.3.6**.....:	See appended Table 8.10	Pass
8.11.3.5	**Cord anchorage**		Pass
	a) Conductors of power supply cord provided with strain relief and insulation protected from abrasion at point of entry to me equipment or a mains connector by a cord anchorage		Pass
	b) Cord anchorage of power supply cord is an insulating material, or		N/A
	– metal, insulated from conductive accessible parts non-protectively earthed by a means of protection, or		N/A
	– metal provided with an insulating lining affixed to cord anchorage		N/A
	c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation		Pass
	d) Screws to be operated when replacing power supply cord do not serve to secure any components		N/A
	e) Conductors of power supply cord arranged to prevent protective earth conductor against strain as long as phase conductors are in contact with their terminals		N/A
	f) Cord anchorage prevents power supply cord from being pushed into me equipment or mains connector		Pass
	Conductors of power supply cord supplied by manufacturer disconnected from terminals or from mains connector and cord subjected 25 times to a pull applied with no jerks, each time for 1 s, on sheath of the value in Table 18 .....:	See appended Table 8.11.3.5	Pass
	Cord subjected to a torque in Table 18 for one minute immediately after pull tests		Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	Cord anchorage did not allow cord sheath to be longitudinally displaced by more than 2 mm or conductor ends to move over a distance of more than 1 mm from their connected position		Pass
	Creepage and clearances not reduced below limits in 8.9		Pass
	It was not possible to push the cord into me equipment or mains connector to an extent the cord or internal parts would be damaged		Pass
8.11.3.6	**Power supply cords protected against excessive bending at inlet opening of equipment**		Pass
	Cord guard complied with test of IEC 60335-1:2001, Clause 25.14, or		N/A
	Me equipment placed such that axis of cord guard projected at an angle of 45° with cord free from stress, and a mass equal 10 x D2 gram attached to the free end of cord (g) .....:	See appended Table 8.11.3.6	Pass
	Cord guard of temperature-sensitive material tested at 23 °C ± 2 °C, and flat cords bent in the plane of least resistance		N/A
	Curvature of the cord radius, immediately after mass attached, was not less than 1.5 x D.....:	See appended Table 8.11.3.6	Pass
8.11.4	**Mains terminal devices**		N/A
8.11.4.1	**Permanently installed and me equipment with non-detachable power supply cord provided with mains terminal devices ensuring reliable connection**		N/A
	Terminals alone are not used to keep conductors in position		N/A
	Terminals of components other than terminal blocks complying with requirements of this Clause and marked accordingly used as terminals intended for external conductors		N/A
	Screws and nuts clamping external conductors do not serve to secure any other component		N/A
8.11.4.2	**Arrangement of mains terminal devices**		N/A
	a) Terminals provided for connection of external cords or power supply cords together with protective earth terminal grouped to provide convenient means of connection		N/A
	d) Mains terminal devices not accessible without use of a tool		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	e) means of protection are not short circuited when one end of a flexible conductor with nominal cross-sectional area is stripped 8 mm and a single free wire is bent in each possible direction		N/A
8.11.4.3	**Internal wiring not subjected to stress and creepage and clearances not reduced after fastening and loosening a conductor of largest cross-sectional area 10 times**		N/A
8.11.4.4	**Terminals with clamping means for a rewireable flexible cord did not require special preparation of conductors and conductors were not damaged and did not slip out when clamping means tightened**		N/A
8.11.4.5	**Adequate space provided inside me equipment designed for fixed wiring or a rewireable power supply cord to allow for connection of conductors**		N/A
	Correct connection and positioning of conductors before access cover verified by an installation test		N/A
8.11.5	**Mains fuses and over-current releases**		Pass
	A fuse or over-current release provided in each supply lead for class i and class ii me equipment with a functional earth connection..:	See appended Table 8.10	Pass
	- in at least one supply lead for other single-phase class ii me equipment.....:		N/A
	– neutral conductor not fused for permanently installed me equipment		N/A
	– fuses or over-current releases omitted due to provision of two means of protection between all parts within mains part		N/A
	Protective devices have adequate breaking capacity based on manufacturer's expectation of the highest branch circuit current and/or prospective short circuit current .....:	See appended Table 8.10	Pass
	A fuse or over-current release not provided in a protective earth conductor		N/A
	Justification for omission of fuses or over-current releases documented .....:		N/A
8.11.6	**Internal wiring of the mains part**		N/A
	a) Cross-sectional area of internal wiring in a mains part between mains terminal device or appliance inlet and protective devices suitable :	No such part	N/A
	b) Cross-sectional area of other wiring in mains part and sizes of tracks on printed wiring circuits are sufficient.....:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

9	**PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS**		Pass
9.2	**Hazards associated with moving parts**		N/A
9.2.1	**When me equipment with moving parts properly installed, used per accompanying documents or under foreseeable misuse, risks associated with moving parts reduced to an acceptable level** .....:	Component, to be evaluated in end product	N/A
	Risk from contact with moving parts reduced to an acceptable level using protective measures, (access, function, shape of parts, energy, speed of motion, and benefits to patient considered)		N/A
	Residual risk associated with moving parts considered acceptable when exposure was needed for me equipment to perform its intended function, and		N/A
	risk controls implemented .....:		N/A
	risk management file includes an assessment of risks associated with moving parts: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)		N/A
	All risks associated with moving parts have been reduced to an acceptable level		N/A
9.2.2	**Trapping zone**		N/A
9.2.2.1	**Me equipment with a trapping zone complied with one or more of the following as feasible** ...:	Component, to be evaluated in end product	N/A
	– Gaps in Clause 9.2.2.2, or		N/A
	– Safe distances in Clause 9.2.2.3, or		N/A
	– guards and other risk control measures in 9.2.2.4, or		N/A
	– Continuous activation in Clause 9.2.2.5		N/A
	Control of relevant motion complied with 9.2.2.6 when implementation of above protective measures were inconsistent with intended use of me equipment or me system		N/A
9.2.2.2	**A trapping zone considered not to present a mechanical hazard when gaps of trapping zone complied with dimensions per Table 20** .....:		N/A
9.2.2.3	**A trapping zone considered not to present a mechanical hazard when distances separating operator, patient, and others from trapping zones exceeded values in ISO 13857:2008** .....:		N/A
9.2.2.4	**Guards and other risk control measures**		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
9.2.2.4.1	**A trapping zone do not to present a mechanical hazard when guards or other risk control measures are of robust construction, not easy to bypass or render non-operational, and did not introduce additional unacceptable risk** .....:		N/A
9.2.2.4.2	**Fixed guards held in place by systems that can only be dismantled with a tool**		N/A
9.2.2.4.3	**Movable guards that can be opened without a tool remained attached when guard was open**		N/A
	– they are associated with an interlock preventing relevant moving parts from starting to move while trapping zone is accessible, and stops movement when the guard is opened,		N/A
	– absence or failure of one of their components prevents starting, and stops moving parts		N/A
	Movable guards complied with any applicable tests		N/A
9.2.2.4.4	**Other risk control designed and incorporated into to the control system stops movement and**		N/A
	– single fault conditions have a second risk control, or		N/A
	me equipment is single fault safe		N/A
9.2.2.5	**Continuous activation**		N/A
	Continuous activation used as a risk control, complies with the following		N/A
	a) movement was in operator's field of view		N/A
	b) movement of me equipment or its parts was possible only by continuous activation of control by operator		N/A
	c) a second risk control provided for single fault condition of continuous activation system, or		N/A
	- the continuous activation system is single fault safe		N/A
9.2.2.6	**Speed of movement(s) positioning parts of me equipment or patient limited to allow operator control of the movement**		N/A
	Over travel of such movement occurring after operation of a control to stop movement, did not result in an unacceptable risk		N/A
9.2.3	**Other mechanical hazards associated with moving parts**		N/A
9.2.3.1	**Controls positioned, recessed, or protected by other means so that they cannot be accidentally actuated**		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	- unless for the intended patient, the usability engineering process concludes otherwise (e.g. patient with special needs), or		N/A
	- activation does not result in an unacceptable risk		N/A
9.2.3.2	**Over travel past range limits of the me equipment prevented** .....:		N/A
	Over travel means provided with mechanical strength to withstand loading in normal condition & reasonably foreseeable misuse .....:		N/A
9.2.4	**Emergency stopping devices**		N/A
	Where necessary to have one or more emergency stopping device(s), emergency stopping device complied with all the following, except for actuating switch capable of interrupting all power .....:		N/A
	a) Emergency stopping device reduced risk to an acceptable level		N/A
	risk management file indicates the use of an emergency stopping device reduces the risk to an acceptable level: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.5)		N/A
	b) Proximity and response of operator to actuate emergency stopping device could be relied upon to prevent harm		N/A
	c) Emergency stopping device actuator was readily accessible to operator		N/A
	d) Emergency stopping device(s) are not part of normal operation of me equipment		N/A
	e) Emergency switching operation or stopping means neither introduced further hazard nor interfered with operation necessary to remove original mechanical hazard		N/A
	f) Emergency stopping device was able to break full load of relevant circuit, including possible stalled motor currents and the like		N/A
	g) Means for stopping of movements operate as a result of one single action		N/A
	h) Emergency stopping device provided with an actuator in red and easily distinguishable and identifiable from other controls		N/A
	i) An actuator interrupting/opening mechanical movements marked on or immediately adjacent to face of actuator with symbol 18 of Table D.1 or “stop”		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	j) Emergency stopping device, once actuated, maintained me equipment in disabled condition until a deliberate action, different from that used to actuate it, was performed		N/A
	k) Emergency stopping device is suitable for its application		N/A
9.2.5	**Means provided to permit quick and safe release of patient in event of breakdown of me equipment or failure of power supply, activation of a risk control measure, or emergency stopping** .....:		N/A
	– and uncontrolled or unintended movement of me equipment that could result in an unacceptable risk prevented		N/A
	– Situations where patient is subjected to unacceptable risks due to proximity of moving parts, removal of normal exit routes, or other hazards prevented		N/A
	– Measures provided to reduce risk to an acceptable level when after removal of counterbalanced parts, other parts of me equipment can move in a hazardous way		N/A
	risk management file includes an assessment of risks to the patient related to breakdown of the me equipment : (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)		N/A
9.3	**Rough surfaces, sharp corners and edges of me equipment that could result in injury or damage avoided or covered** .....:	No rough surface, sharp corner or edge.	Pass
9.4	**Instability hazards**		N/A
9.4.1	**Me equipment and its parts, other than fixed, for placement on a surface did not overbalance (tip over) or move unexpectedly in normal use**		N/A
9.4.2	**Instability – overbalance**		N/A
9.4.2.1	**Me equipment or its parts did not overbalance when prepared per accompanying documents, or when tested** .....:	Component, to be evaluated in end product	N/A
9.4.2.2	**Instability excluding transport**		N/A
	Me equipment or its did not overbalance when placed in different positions of normal use,.....:		N/A
	A warning provided when overbalance occurred during 10° inclined plane test		N/A
9.4.2.3	**Instability from horizontal and vertical forces**		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	a) Me equipment or its parts with a mass of 25kg or more, intended to be used on the floor, didn't overbalance due to pushing, leaning against it		N/A
	Surfaces of me equipment or its parts where a risk of overbalancing exists from pushing, etc., permanently marked with a warning of the risk		N/A
	Me equipment did not overbalance when tested according to Cl. 9.4.2.3 a)		N/A
	b) Me equipment, for use on the floor or on a table, did not overbalance due to sitting or stepping		N/A
	Me equipment or its parts, for use on the floor or on a table, where risk of overbalancing exists, permanently marked with the risk warning .....:	Component, to be evaluated in end product	N/A
	Me equipment did not overbalance when tested according to Cl. 9.4.2.3b) .....:		N/A
9.4.2.4	**Castors and wheels**		N/A
9.4.2.4.1	**Means used for transportation of mobile me equipment did not result in an unacceptable risk when mobile me equipment moved or parked in normal use**		N/A
9.4.2.4.2	**Force required to move mobile me equipment did not exceed 200 N** .....:	Component, to be evaluated in end product	N/A
9.4.2.4.3	**Mobile me equipment exceeding 45 kg able to pass over threshold** .....:		N/A
9.4.3	**Instability from unwanted lateral movement (including sliding)**		N/A
9.4.3.1	**a) Brakes of power-driven mobile me equipment normally activated and could only be released by continuous actuation of a control**		N/A
	b) Mobile me equipment provided with locking means to prevent unwanted movements		N/A
	c) No unwanted lateral movement resulted when mobile me equipment placed in its transport position when test per 9.4.3.1		N/A
9.4.3.2	**Instability excluding transport**		N/A
	a) mobile me equipment provided with wheel locks or braking system compliant with 5° tilt test .....:		N/A
	b) mobile me equipment provided with wheel locks or braking system compliant with lateral stability test		N/A
9.4.4	**Grips and other handling devices**		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	a) Me equipment with a mass of over 20 kg requiring lifting in normal use or transport provided with suitable handling means, or accompanying documents specify safe lifting method		N/A
	Handles, suitably placed to enable me equipment or its part to be carried by two or more persons and by examination of equipment, its part, or accompanying documents		N/A
	b) Portable me equipment with a mass > 20 kg provided with one or more carrying-handles suitably placed to enable carrying by two or more persons as confirmed by actual carrying		N/A
	c) Carrying handles and grips and their means of attachment withstood loading test.....:		N/A
9.5	**Expelled parts hazard**		N/A
9.5.1	**Suitability of means of protecting against expelled parts determined by assessment and examination of risk management file : (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)**	Component, to be evaluated in end product	N/A
	All identified risks associated with expelled parts mitigated to an acceptable level		N/A
9.5.2	**Cathode Ray tube(s) complied with IEC 60065:2001, Clause 18, or IEC 61965**.....:		N/A
9.6	**Acoustic energy (including infra- and ultrasound) and vibration**		N/A
9.6.1	**Human exposure to acoustic energy and vibration from me equipment doesn't result in unacceptable risk and**		N/A
	If necessary, confirmed in risk management file including audibility of auditory alarm signals, and patient sensitivity.....:		N/A
	If necessary, confirmed in risk management file including audibility of auditory alarm signals, patient sensitivity, and (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)		N/A
	All identified risks mitigated to an acceptable level		N/A
9.6.2	**Acoustic energy**		N/A
9.6.2.1	**Patient, operator, and other persons are not exposed to acoustic energy from me equipment in normal use**	Component, to be evaluated in end product	N/A
	– 80 dBA for a cumulative exposure of 24 h over a 24 h period (dBA).....:		-
	- 83 dBA (when halving the cumulative exposure time) (dBA).....:		-

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Clause	Requirement + Test	Result - Remark	Verdict
	– 140 dBC (peak) sound pressure level for impulsive or impact acoustic energy (dB) .....:		-
9.6.2.2	**Risk management file examined : (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)**		N/A
9.6.3	**Hand-transmitted vibration**		N/A
	Means provided to protect patient and operator when hand-transmitted frequency-weighted r.m.s. acceleration generated in normal use exceeds specified values		N/A
	– 2.5 m/s2 for a cumulative time of 8 h during a 24 h period (m/s2) .....:		N/A
	– Accelerations for different times, inversely proportional to square root of time (m/s2) .....:		N/A
9.7	**Pressure vessels and parts subject to pneumatic and hydraulic pressure**		N/A
9.7.2	**Pneumatic and hydraulic parts of me equipment or accessories met requirements based on examination of risk management file : (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)**	Component, to be evaluated in end product	N/A
	– No unacceptable risk resulted from loss of pressure or loss of vacuum		N/A
	– No unacceptable risk resulted from a fluid jet caused by leakage or a component failure		N/A
	– Elements of me equipment or an accessory, especially pipes and hoses leading to an unacceptable risk protected against harmful external effects		N/A
	– Reservoirs and similar vessels leading to an unacceptable risk are automatically depressurized when me equipment is isolated from its power supply		N/A
	Means provided for isolation, or local depressurizing reservoirs and similar vessels, and pressure indication when above not possible		N/A
	– All elements remaining under pressure after isolation of me equipment or an accessory from its power supply resulting in an unacceptable risk provided with clearly identified exhaust devices, and a warning to depressurize these elements before setting or maintenance activity		N/A
9.7.4	**maximum equipment pressure did not exceed maximum permissible working pressure for the part, except allowed for pressure relief devices in 9.7.7confirmed by inspection of the manufacturer's data for the component, me equipment, and by functional tests** .....:	Component, to be evaluated in end product	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
9.7.5	**A pressure vessel withstood a hydraulic test pressure when maximum equipment pressure was more than 50 kPa, and product of maximum equipment pressure and volume was more than 200 kPa** .....:		N/A
9.7.6	**Pressure-control device regulating pressure in me equipment with pressure-relief device completed 100,000 cycles of operation under rated load and prevented pressure from exceeding 90 % of setting of pressure-relief device in different conditions of normal use** .....:	Component, to be evaluated in end product	N/A
9.7.7	**Pressure-relief device(s) used where maximum permissible working pressure could otherwise be exceeded met the following, as confirmed by manufacturer's data, me equipment, risk management file, and functional tests** .....:	Component, to be evaluated in end product	N/A
	a) Connected as close as possible to pressure vessel or parts of system it is to protect		N/A
	b) Installed to be readily accessible for inspection, maintenance, and repair		N/A
	c) Could be adjusted or rendered inoperative without a tool		N/A
	d) With discharge opening located and directed as to not to release material towards any person		N/A
	e) With discharge opening located and directed as to not to deposit material on parts that could result in an unacceptable risk		N/A
	f) Adequate discharge capacity provided to ensure that pressure will not exceed maximum permissible equipment pressure of system it is connected to by more than 10 % when failure occurs in control of supply pressure		N/A
	g) No shut-off valve provided between a pressure-relief device and parts it is to protect		N/A
	h) Min number of cycles of operation 100 000, except for one-time use devices (bursting disks)		N/A
	risk management file includes an assessment of the risks associated with the discharge opening of the pressure relief device : ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)		N/A
9.8	**Hazards associated with support systems**		N/A
9.8.1	**Me equipment parts designed to support loads or provide actuating forces when a mechanical fault could constitute an unacceptable risk** .....:	Component, to be evaluated in end product	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– Construction of support, suspension, or actuation system complied with Table 21 and total load		N/A
	– Means of attachment of accessories prevent possibility of incorrect attachment that could result in an unacceptable risk		N/A
	– Risk analysis of support systems included mechanical hazards from static, dynamic, vibration, foundation and other movements, impact and pressure loading, temperature, environmental, manufacture and service conditions : **(ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)**		N/A
	– Risk analysis included effects of failures such as excessive deflection, plastic deformation, ductile/brittle fracture, fatigue fracture, instability (buckling), stress-assisted corrosion cracking, wear, material creep and deterioration, and residual stresses from manufacturing processes		N/A
	– Instructions on attachment of structures to a floor, wall, ceiling, included in accompanying documents making adequate allowances for quality of materials used to make the connection and list the required materials		N/A
	Additional instructions provided on checking adequacy of surface of structure parts will be attached to		N/A
9.8.2	**Support systems maintain structural integrity during expected service life, and tensile safety factors are not less than in Table 21, except when an alternative method used to demonstrate structural integrity throughout expected service life, or for a foot rest**		N/A
	Compliance with 9.8.1 and 9.8.2 confirmed by examination of me equipment, risk management file, specifications and material processing.....:		N/A
	risk management file includes an assessment of the structural integrity of support system : **(ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)**		N/A
	All identified risks are mitigated to an acceptable level		N/A
	When test was conducted, testing consisted of application of a test load to support assembly equal to total load times required tensile safety factor while support assembly under test was in equilibrium after 1 min, or not resulted in an unacceptable risk .....:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Where the equipment is not at equilibrium after 1 min, the risk management file includes an assessment of the test results : **(ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)**		N/A
9.8.3	**Strength of patient or operator support or suspension systems**		N/A
9.8.3.1	**Me equipment parts supporting or immobilizing patients presents no unacceptable risk of physical injuries and accidental loosening of secured joints** .....:		N/A
	risk management file includes assessment of the risks associated with physical injuries and accidental loosening of fixings : **(ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)**		N/A
	Safe working load of me equipment or its parts supporting or suspending patients or operators is sum of mass of patients or mass of operators plus mass of accessories supported by me equipment or its parts		N/A
	Supporting and suspending parts for adult human patients or operators designed for a patient or operator with a min mass of 135 kg and accessories with a min mass of 15 kg, unless stated by manufacturer		N/A
	Maximum mass of patient included in safe working load of me equipment or its parts supporting or suspending patients adapted when manufacturer specified applications		N/A
	Max allowable patient mass < 135 kg marked on me equipment and stated in accompanying documents		N/A
	Max allowable patient mass over 135 kg stated in accompanying documents		N/A
	Examination of markings, accompanying documents, and risk management file confirmed compliance .....:		N/A
9.8.3.2	**a) Entire mass of patient or operator distributed over an area of 0.1 m2 on a foot rest temporarily supporting a standing patient or operator** .....:		N/A
	Compliance confirmed by examination of me equipment specifications of materials and their processing, and tests.....:		N/A
	b) Deflection of a support surface from patient or operator loading on an area of support/ suspension where a patient or operator can sit did not result in an unacceptable risk		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

	Compliance confirmed by examination of me equipment, specifications of materials and their processing, and by a test.....:		N/A
9.8.3.3	**Dynamic forces that can be exerted on equipment parts supporting or suspending a patient or operator in normal use maintained basic safety and essential performance confirmed test**		N/A
9.8.4	**Systems with mechanical protective devices**		N/A
9.8.4.1	**a) A mechanical protective device provided for the support system**		N/A
	b) Mechanical protective complies with the requirements as follows .....:		N/A
	– Designed based on total load		N/A
	– Has tensile safety factors for all parts not less than Table 21, row 7		N/A
	– Activated before travel produced an unacceptable risk		N/A
	– Considers Clauses 9.2.5 and 9.8.4.3		N/A
	Compliance confirmed by examination of me equipment over travel calculations and evaluation plus functional tests.....:		N/A
9.8.4.2	**Activation of mechanical protective device is made obvious to operator when me equipment can still be used after failure of suspension or actuation means and activation of a mechanical protective device**		N/A
	Mechanical protective device requires use of a tool to be reset or replaced		N/A
9.8.4.3	**Mechanical protective device intended to function once**		N/A
	–use of me equipment not possible until replacement of mechanical protective device...:		N/A
	– Accompanying documents provided with required information on replacement by service personal		N/A
	– Me equipment permanently marked with safety sign 2 of Table D.		N/A
	– Marking is adjacent to mechanical protective device		N/A
	– Compliance confirmed by examination and following test.....:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	A chain, cable, band, spring, belt, jack screw nut, pneumatic or hydraulic hose, structural part or the like, employed to support a load, defeated by a convenient means causing maximum normal load to fall from most adverse position permitted by construction of me equipment		N/A
	Load included safe working load in 9.8.3.1 when system was capable of supporting a patient or operator		N/A
	No evidence of damage to mechanical protective device affecting its ability to perform its intended function		N/A
9.8.5	**Systems without mechanical protective devices**		N/A
	Support Systems does not require mechanical protective devices .....:		N/A
	risk management file includes an assessment of risks associated with wear on the support system : **(ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)**		N/A
10	**PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS**		N/A
10.1	**X-Radiation**		N/A
10.1.1	**The air kerma did not exceed 5 µGy/hat 5 cm from surface of me equipment**.....:	Component, to be evaluated in end product	N/A
	Annual exposure reduced taking into account the irradiated body part, national regulations, and/or international recommendations for me equipment that has permanent proximity to a patient as part of the intended use		N/A
10.1.2	**Risk from unintended X-radiation from me equipment producing X-radiation for diagnostic and therapeutic purposes addressed application of applicable particular and collateral standards, or**.....:		N/A
	risk management process as indicated in risk management file: **(ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)**		N/A
10.2	**Risk associated with alpha, beta, gamma, neutron, and other particle radiation, addressed in risk management process as shown in risk management file :** **(ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)**		N/A
10.3	**The power density of unintended microwave radiation at frequencies between 1 GHz and 100 GHz does not exceed 10 W/m2**		N/A
	Microwave radiation is propagated intentionally		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
10.4	**Relevant requirements of IEC 60825-1:2014 applied to lasers including laser diodes, laser light barriers or similar with a wavelength range of 180nm to 1 mm.**		N/A
10.5	**Risk associated with visible electromagnetic radiation other than emitted by lasers when applicable, addressed in risk management process as indicated in risk management file : (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)**		N/A
10.6	**Risk associated with infrared radiation other than emitted by lasers addressed in risk management process as indicated in risk management file : (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)**		N/A
10.7	**Risk associated with ultraviolet radiation other than emitted by lasers and leds addressed in risk management process as indicated in risk management file : (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)**		N/A
11	**PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS**		Pass
11.1	**Excessive temperatures in me equipment**		Pass
11.1.1	**Temperatures on accessible parts did not exceed values in Tables 22 and** .....:	See appended Table 11.1.1	Pass
	Surfaces of test corner did not exceed 90 °C		Pass
	thermal cut-outs did not operate in normal condition		N/A
	risk management file includes an assessment of the duration of contact for all applied parts and accessible parts : (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)		N/A
11.1.2	**Temperature of applied parts**		N/A
11.1.2.1	**applied parts (hot or cold intended to supply heat to a patient comply** .....:	Component, to be evaluated in end product	N/A
	Clinical effects determined and documented in the risk management file (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)		N/A
	Temperature (hot or cold) of applied parts intended to supply heat to a patient disclosed in the instructions for use		N/A
11.1.2.2	**applied parts not intended to supply heat to a patient complies with the limits of Table 24 in normal condition and single fault condition**.....:	Component, to be evaluated in end product	N/A
	applied parts surface temperature exceeds 41°C disclosed in the instruction manual .....:		N/A
	Maximum Temperature .....:		-

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Clause	Requirement + Test	Result - Remark	Verdict
	Conditions for safe contact, e.g. duration or condition of the patient.....:		-
	Clinical effects with respect to characteristics taken or surface pressure documented in the risk management file (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)		N/A
	applied parts surface temperature of equal to or less than 41°C		N/A
	Analysis documented in the risk management file show that applied part temperatures are not affected by operation of the me equipment including single fault conditions. Measurement of applied part temperature according to 11.1.3 is not conducted.....:		N/A
	Surfaces of applied parts that are cooled below ambient temperatures evaluated in the risk management process :(ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)		N/A
11.1.3	**Measurements not made when engineering judgment and rationale by manufacturer indicated temperature limits could not exceed, as documented in risk management file :(ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)**	Test conducted	N/A
	Test corner not used where engineering judgment and rationale by manufacturer indicated test corner will not impact measurements, as documented in risk management file :(ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)		N/A
	Probability of occurrence and duration of contact for parts likely to be touched and for applied parts documented in risk management file :(ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	RMF Reference to specific risks: doc. No. GT-RM2013-010, version A.2, chapter 6.3, Hazard ID 10 (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4).	Pass
	e) Where thermal regulatory devices make this method inappropriate, alternative methods for measurement are justified in the risk management file.....:		N/A
11.1.4	**Guards preventing contact with hot or cold accessible surfaces removable only with a tool**		N/A
11.2	**Fire prevention**		Pass
11.2.1	**Enclosure has strength and rigidity necessary to prevent a fire and met mechanical strength tests for enclosures in 15.3**		Pass
11.2.2	**Me equipment and me systems used in conjunction with oxygen rich environments**		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
11.2.2.1	**Risk of fire in an oxygen rich environment reduced by means limiting spread of**.....:	Component, not evaluated for use with Oxygen Rich Environment	N/A
	a) No sources of ignition discovered in an oxygen rich environment under any of the following conditions		N/A
	1) when temperature of material raised to its ignition temperature		N/A
	2) when temperatures affected solder or solder joints causing loosening, short circuiting, or other failures causing sparking or increasing material temperature to its ignition temperature		N/A
	3) when parts affecting safety cracked or changed outer shape exposing temperatures higher than 300°C or sparks due to overheating		N/A
	4) when temperatures of parts or components exceeded 300°C, atmosphere was 100 % oxygen, contact material solder, and fuel cotton		N/A
	5) when sparks provided adequate energy for ignition by exceeding limits of Figs 35 to 37 (inclusive), atmosphere was 100 % oxygen, contact material solder, and fuel cotton		N/A
	Deviations from worst case limits in 4) and 5) above based on lower oxygen concentrations or less flammable fuels justified and documented in risk management file:(ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)		N/A
	Alternative test in this clause did not identify existence of ignition sources at highest voltage or current, respectively.....:		N/A
	A safe upper limit determined by dividing upper limit of voltage or current, respectively, with safety margin factor of three.....:		N/A
	b) Residual risk of fire in an oxygen rich environment as determined by application of risk management process is based on following configurations, or in combination : (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)		N/A
	1) Electrical components in an oxygen rich environment provided with power supplies having limited energy levels lower than those considered sufficient for ignition in 11.2.2.1 a) as determined by examination, measurement or calculation of power, energy, and temperatures in normal and single fault conditions identified in 11.2.3 .....:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	2) Max oxygen concentration measured until it did not exceed 25 % in ventilated compartments with parts that can be a source of ignition only in single fault condition and can be penetrated by oxygen due to an undetected leak (%).....:		N/A
	3) A compartment with parts or components that can be a source of ignition only under single fault condition separated from another compartment containing an oxygen rich environment by sealing all joints and holes for cables, shafts, or other purposes		N/A
	Effect of possible leaks and failures under single fault condition that could cause ignition evaluated using a risk assessment to determine maintenance intervals by examination of documentation and risk management file .....:		N/A
	4) Fire initiated in enclosure of electrical components in a compartment with oxygen rich environment that can become a source of ignition only under single fault conditions self-extinguished rapidly and no hazardous amount of toxic gases reached patient as determined by analysis of gases.....:		N/A
11.2.2.2	**risk of ignition did not occur, and oxygen concentration did not exceed 25% in immediate surroundings due to location of external exhaust outlets of an oxygen rich environment**		N/A
11.2.2.3	**Electrical connections within a compartment containing an oxygen rich environment under normal use did not produce sparks**		N/A
	– Screw-attachments protected against loosening during use by varnishing, use of spring washers, or adequate torques		N/A
	– Soldered, crimped, and pin-and-socket connections of cables exiting enclosure include additional mechanical securing means		N/A
11.2.3	**Single fault conditions related to oxygen rich environments me equipment and me systems considered**		N/A
	– Failure of a ventilation system constructed in accordance with 11.2.2.1 b) 2).....:		N/A
	– Failure of a barrier constructed in accordance with 11.2.2.1 b) 3).....:		N/A
	– Failure of a component creating a source of ignition (as defined in 11.2.2.1 a) .....:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– Failure of solid insulation or creepage and clearances providing equivalent of at least one means of patient protection but less than two means of patient protection that could create a source of ignition defined in 11.2.2.1 a) .....:		N/A
	– Failure of a pneumatic component resulting in leakage of oxygen-enriched gas.....:		N/A
11.3	**Constructional requirements for fire enclosures of me equipment**		Pass
	Me equipment met this clause for alternate means of compliance with selected hazardous situations and fault conditions in 13.1.2 .....:	See 8.10 table	Pass
	Constructional requirements were met, or		Pass
	- constructional requirements specifically analysed in risk management file .. : (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)		N/A
	Justification, when requirement not met .....:		N/A
	a) Flammability classification of insulated wire and connectors within fire enclosure is minimum V-2, , when test in accordance with IEC 60695-11-10 or.....:	See appended Table 8.10	Pass
	insulated with PVC, TFE, PTFE, FEP, polychloroprene or polyimide as determined by examination of data on materials .....:		N/A
	Flammability classification of printed circuit boards, and insulating material on which components are mounted is V-2, or better, based on IEC 60695-11-10 as decided by examination of materials data.....:		N/A
	If no Certification, V tests based on IEC 60695-11-10 conducted on 3 samples of complete parts (or sections of it), including area with min. thickness, ventilation openings		N/A
	b) Fire enclosure met following .....:	No openings	Pass
	1) No openings at bottom or, as specified in Fig 39, constructed with baffles as in Fig 38, or made of perforated metal as in Table 25, or a metal screen with a mesh ≤ 2 × 2 mm centre to centre and wire diameter of at least 0.45 mm		Pass
	2) No openings on the sides within the area included within the inclined line C in Fig 39 or made of perforated metal as in Table 25, or a metal screen with a mesh ≤ 2 × 2 mm centre to centre and wire diameter of at least 0.45 mm		Pass
	3) Enclosure, baffles, and flame barriers have adequate rigidity and are made of appropriate metal or of non-metallic materials .....:	See appended Table 8.10	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
11.4	**Me equipment and me systems intended for use with flammable anaesthetics**		N/A
	Me equipment, me systems and parts described in accompanying documents for use with flammable with Annex G		N/A
11.5	**Me equipment and me systems intended for use in conjunction with flammable agents**		N/A
	Manufacturer's risk management process addresses possibility of fire and associated mitigations as confirmed by examination of risk management file :(ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	Not evaluated for use in the presence of flammable agent	N/A
11.6	**Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the me equipment**		Pass
11.6.1	**Sufficient degree of protection provided against overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection and sterilization, and compatibility with substances used with me equipment** .....:	See Appended Table 11.6.1	Pass
11.6.2	**Overflow in me equipment**		N/A
	me equipment incorporates a reservoir or liquid storage that did not wet any means of protection, nor result in the loss of basic safety or essential performance.....:		N/A
	Maximum fill level is indicated by marking on the me equipment and a warning or safety notice is given, no hazardous situation (as specified in 13.1) or unacceptable risk due to overflow developed when the reservoir or liquid storage chamber is filled to its maximum capacity and the transportable me equipment is tilted through an angle of 10°, or for mobile me equipment exceeding 45 kg, is moved over a threshold as described in 9.4.2.4.3.		N/A
	No warning or safety notice provided regarding the maximum fill level, no hazardous situation (as specified in 13.1) or unacceptable risk due to overflow developed when the reservoir or liquid storage chamber was filled to 15 % above the maximum capacity and the transportable me equipment was tilted through an angle of 10°, or in mobile me equipment exceeding 45 kg, was moved over a threshold as described in 9.4.2.4.3.		N/A
11.6.3	**Spillage on me equipment and me system**		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Me equipment and me systems handling liquids constructed that spillage does not wet parts as determined by review of the risk management file and test:(ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)		N/A
	risk analysis identifies the type of liquid, volume, duration and location of the spill .....:		N/A
11.6.5	**Ingress of water or particulate matter into me equipment and me systems**		Pass
	Me equipment with IP Code placed in least favourable position of normal use and subjected to tests of IEC 60529 (IP Code).....:	See Appended Table 11.6.1	Pass
	Me equipment met dielectric strength and leakage current tests and there were no bridging of insulation or electrical components that could result in the loss of basic safety or essential performance in normal condition or in combination with a single fault condition .....:	See appended Tables 8.7, 8.8.3	Pass
11.6.6	**Cleaning and disinfection of me equipment and me systems**		N/A
	Me equipment/me system and their parts and accessories cleaned or disinfected using methods specified in instructions for use.....:	Component, to be evaluated in end product	N/A
	Effects of multiple cleanings/disinfections during expected service life of equipment evaluated by manufacturer.....:		N/A
11.6.7	**Sterilization of me equipment and me systems**		N/A
	Me equipment, me systems and their parts or accessories intended to be sterilized assessed and documented and compliant with tests.....:		N/A
	risk management file includes an assessment of the risks associated with any deterioration following sterilization:(ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)		N/A
11.6.8	**risks associated with compatibility of substances used with me equipment addressed in risk management process:(ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)**	Component, to be evaluated in end product	N/A
11.7	**Me equipment, me system, and accessories coming into direct or indirect contact with biological tissues, cells, or body fluids assessed and documented**		N/A
11.8	**Interruption and restoration of power supply did not result in a loss of basic safety or essential performance**		N/A
12	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
12.1	**risks associated with accuracy of controls and instruments stated : (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)**	Component, to be evaluated in end product	N/A
12.2	**Risk of poor usability, including identification, marking, and documents addressed in a usability engineering**.....:		N/A
12.3	**manufacturer implemented an alarm system compliant with IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020** .....:		N/A
12.4	**Protection against hazardous output**		N/A
12.4.1	**RISKS associated with hazardous output arising from intentional exceeding of safety limits addressed in RISK MANAGEMENT PROCESS: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)**		N/A
12.4.2	**- need for indication associated with hazardous output addressed in RISK MANAGEMENT PROCESS: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4))**		N/A
12.4.3	**risks associated with accidental selection of excessive output values for me equipment with a multi-purpose unit addressed in risk management process :(ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)**		N/A
12.4.4	**risks associated with incorrect output addressed in risk management process :(ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)**		N/A
12.4.5	**Diagnostic or therapeutic radiation**		N/A
12.4.5.1	**Adequate provisions to protect operators, patients, other persons and sensitive devices in vicinity of unwanted or excessive radiation**		N/A
	Radiation safety ensured by compliance with requirements of appropriate standards		N/A
12.4.5.2	**me equipment and me systems designed to produce X-radiation for diagnostic imaging purposes complied with IEC 60601-1-3**.....:		N/A
12.4.5.3	**risks associated with radiotherapy addressed in risk management process as : (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)**		N/A
12.4.5.4	**risks associated with me equipment producing diagnostic or therapeutic radiation other than diagnostic X-rays and radiotherapy addressed in risk management process as : (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)**		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

12.4.6	**risks associated with diagnostic or therapeutic acoustic pressure addressed in risk management : (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)**		N/A
13	**HAZARDOUS SITUATIONS AND FAULT CONDITIONS**		Pass
13.1	**Specific hazardous situations**		Pass
13.1.2	**Emissions, deformation of enclosure or exceeding maximum temperature**		Pass
	– Emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities did not occur		Pass
	– Deformation of enclosure impairing compliance with 15.3.1 did not occur		Pass
	– Temperatures of applied parts did not exceed allowable values in Table 24.....:	Component, to be evaluated in end product	N/A
	– Temperatures of Accessible PARTS that are likely to be touched, but not intended to be touched did not exceed limits in Table 34 .....:		N/A
	- Temperatures of ACCESSIBLE PARTS intended to be touched did not exceed limits in Table 23		Pass
	–Allowable values for "other components and materials" in Table 22 times 1.5 minus 12.5 °C were not exceeded		Pass
	Limits for windings in Tables 26, 27, and 31 not exceeded		Pass
	Table 22 not exceeded in all other cases		Pass
	Temperatures measured according to 11.1.3		Pass
	Single fault conditions in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances, not applied to parts and components where.....:	See below	Pass
	– Supply circuit was unable to supply 15 W one minute after 15 W drawn from supply circuit in single fault condition ....:		N/A
	- or secondary circuits mounted on materials with a minimum flame rating of -V1, and		N/A
	- Secondary circuits energized by less than 60 Vdc, 42.4 Vpeak in NC and SFC, and		N/A
	- Secondary circuits limited to 100 VA or 6000 J in NC and SFC, and		N/A
	- Wire insulation in secondary circuits of types PVC, TFE, PTFE, FEP, polychloroprene or polybromide		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	- or components in the circuit have high integrity characteristics.....:		N/A
	– or parts and components completely contained within a fire enclosure complying with 11.3 as verified by review of design documentation		Pass
	After tests of this Clause, settings of thermal cut-outs and over-current releases did not change sufficiently to affect their safety function	See appended Table 13.1.2	Pass
13.1.3	**– limits for leakage current in single fault condition did not exceed** .....:	See appended Table 8.7	Pass
	– voltage limits for accessible parts and applied parts did not exceed.....:	See appended Table 8.7	Pass
13. 2	**Single fault conditions**		Pass
13.2.1	**During the application of the single fault conditions listed in 13.2.2 to 13.2.13 (inclusive), the normal conditions identified in 8.1 a) also applied in the least favourable combination**		Pass
	me equipment complied with 13.2.2 -13.2.12.....:	See appended Table 13.2	Pass
	risk management file includes an assessment of risks associated with leakage of liquid in a single fault condition:(ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)		N/A
	risk management file defines the appropriate test conditions .....:		N/A
13.2.13	**Me equipment remained safe after tests of 13.2.13.2 to 13.2.13.4, and cooling down to within 3 °C of test environment temperature**		N/A
	Me equipment examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted		N/A
13.2.13.2	**Me equipment with heating elements**		N/A
	a 1) thermostatically controlled me equipment with heating elements for building-in, r for unattended operation, or with a capacitor not protected by a fuse connected in parallel with thermostat contacts met tests		N/A
	a 2) me equipment with heating elements rated for non-continuous operation met tests		N/A
	a 3) other me equipment with heating elements met test		N/A
	When more than one test was applicable to same me equipment, tests performed consecutively		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Heating period stopped when a heating element or an intentionally weak part of a non-self-resetting thermal cut-out ruptured, or current interrupted before thermal stability without possibility of automatic restoration		N/A
	Test repeated on a second sample when interruption was due to rupture of a heating element or an intentionally weak part		N/A
	Both samples met 13.1.2, and open circuiting of a heating element or an intentionally weak part in second sample not considered a failure by itself		N/A
	b) Me equipment with heating elements without adequate heat discharge, and supply voltage set at 90 or 110 % of rated supply voltage, least favourable of the two (V).....:		N/A
	Operating period stopped when a non-self-resetting thermal cut-out operated, or current interrupted without possibility of automatic restoration before thermal stability		N/A
	Me equipment switched off as soon as thermal stability established and allowed to cool to room temperature when current not interrupted		N/A
	Test duration was equal to rated operating time for non-continuous operation		N/A
	c) Heating parts of me equipment tested with me equipment operated in normal condition at 110 % of rated supply voltage and as in 11.1, and		N/A
	1) Controls limiting temperature in normal condition disabled, except thermal cut-outs		N/A
	2) When more than one control provided, they were disabled in turn		N/A
	3) Me equipment operated at rated duty cycle until thermal stability achieved, regardless of rated operating time		N/A
13.2.13.3	**Me equipment with motors**		N/A
	a 1) For the motor part of the me equipment, compliance checked by tests of 13.2.8- 13.2.10, 13.2.13.3 b), 13.2.13.3 c), and 13.2.13.4, as applicable		N/A
	To determine compliance with 13.2.9 and 13.2.10 motors in circuits running at 42.4 V peak a.c./ 60 V d.c. or less are covered with a single layer of cheesecloth which did not ignite during the test		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	a 2) Tests on me equipment containing heating parts conducted at prescribed voltage with motor & heating parts operated simultaneously to produce the least favourable condition		N/A
	a 3) Tests performed consecutively when more tests were applicable to the same me equipment		N/A
	b) Motor met running overload protection test of this clause when .....:		N/A
	1) it is intended to be remotely or automatically controlled by a single control device with no redundant protection, or		N/A
	2) it is likely to be subjected to continuous operation while unattended		N/A
	Motor winding temperature determined during each steady period and maximum value did not exceed Table 27 (Insulation Class, Maximum temperature measured °C).....:		N/A
	Motor removed from me equipment and tested separately when load could not be changed in appropriate steps		N/A
	Running overload test for motors operating at 42.4 V peak a.c./60 V d.c. or less performed only when examination and review of design indicated possibility of an overload		N/A
	Test not conducted where electronic drive circuits maintained a substantially constant drive current		N/A
	Test not conducted based on other justifications (justification).....:		N/A
	c) Me equipment with 3-phase motors operated with normal load, connected to a 3-phase supply mains with one phase disconnected, and periods of operation per 13.2.10		N/A
13.2.13.4	**Me equipment rated for non-continuous operation**		N/A
	Me equipment (other than hand-held) operated under normal load and at rated voltage or at upper limit of rated voltage range until increase in temperature was ≤ 5 °C in one hour, or a protective device operated		N/A
	When a load-reducing device operated in normal use, test continued with me equipment running idle		N/A
	Motor winding temperatures did not exceed values in 13.2.10 .....:		N/A
	Insulation Class .....:		-

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Clause	Requirement + Test	Result - Remark	Verdict
	Maximum temperature measured (°C).....:		-
14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**		N/A
14.1	**Requirements in 14.2 to 14,12 not applied to pems when it provides no functionality necessary for basic safety or essential performance, or**	Component, to be evaluated in end product	N/A
	- when application of risk management showed that failure of pess does not lead to unacceptable risk .....:		N/A
	risk management file contains an assessment of risks associated with the failure of the pess:(ISO 14971 Cl. 5.2-5.5, 6)		N/A
	Requirements of 14.13 not applied to pems intended to be incorporated into an it network		N/A
	When the requirements of 14.2 to 14.13 apply, the requirements of IEC 62304:2006 and IEC 62304:2006/amd1:2015 clause 4.3, 5, 7, 8 and 9 apply for the development or modification of software of each pess		N/A
	Software development process for Software Classification applied in accordance with Clause 4.3 and 4.4 of IEC 62304:2006 and IEC 62304:2006/amd1:2015.....:		N/A
	Software development process applied according to Clause 5 of IEC 62304:2006 and IEC 62304:2006/amd1:2015.....:		N/A
	Software development process for Software risk management applied according to Clause 7 of IEC 62304:2006 and IEC 62304:2006/amd1:2015.....:		N/A
	Software development process Configuration Management applied according to Clause 8 of IEC 62304:2006 and IEC 62304:2006/ amd1:2015 .....:		N/A
	Software development process for Software Problem Resolution applied according to Clause 9 of IEC 62304:2006 and IEC 62304:2006/amd1:2015.....:		N/A
14.2	**Documents required by Clause 14 reviewed, approved, issued and revised according to a formal document control process** .....:		N/A
14.3	**Risk management plan required by 4.2.2 includes reference to pems validation plan**		N/A
14.4	**A pems development life-cycle including a set of defined milestones has been documented**		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	At each milestone, activities to be completed, and verification methods to be applied to activities have been defined		N/A
	Each activity including its inputs and outputs defined, and each milestone identifies risk management activities that must be completed before that milestone		N/A
	Pems development life-cycle tailored for a specific development by making plans detailing activities, milestones		N/A
	Pems development life-cycle includes documentation requirements		N/A
14.5	**A documented system for problem resolution within and between all phases and activities of pems development life-cycle has been developed and maintained**		N/A
14.6	**Risk management process**		N/A
14.6.1	**Manufacturer considered hazards associated with software and hardware aspects of pems including those associated with the incorporating pems into an it-network, components of third-party origin, legacy subsystems when compiling list of known or foreseeable hazards** .....:		N/A
	risk management file includes known or foreseeable hazards associated with software, hardware, incorporation of the pems into an it-network, components of 3rd party origin and legacy subsystems:(ISO 14971 Cl. 5.3)		N/A
14.6.2	**Suitably validated tools and procedures assuring each risk control measure reduces identified risk(s) satisfactorily provided in addition to pems requirements in Clause 4.2.2**.:		N/A
	risk management file documents the suitability of tools and procedures to validate each risk control measure:(ISO 14971 Cl. 7.1)		N/A
14.7	**A documented requirement specification for pems and each of its subsystems (e.g. for a pess) which includes essential performance and risk control measures implemented by that system or subsystem:(ISO 14971 Cl. 7.2)**		N/A
14.8	**An architecture satisfying the requirement is specified for pems and each of subsystems :(ISO 14971 Cl. 7.2)**		N/A
14.9	**Design is broken up into sub systems and descriptive data on design environment documented** .....:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
14.10	**A verification plan containing the specified information used to verify and document functions implementing basic safety, essential performance, or risk control measures:(ISO 14971 Cl. 7.2)**		N/A
	– milestone(s) when verification is to be performed for each function		N/A
	– selection and documentation of verification strategies, activities, techniques, and appropriate level of independence of the personnel performing the verification		N/A
	– selection and utilization of verification tools		N/A
	– coverage criteria for verification		N/A
	The verification performed according to the verification plan and results of the verification activities documented		N/A
14.11	**A pems validation plan containing validation of basic safety & essential performance** .....:		N/A
	The pems validation performed according to the pems validation plan with results of pems validation activities and methods used for pems validation documented		N/A
	The person with overall responsibility for pems validation is independent		N/A
	All professional relationships of members of pems validation team with members of design team documented in risk management file (ISO 14971 Cl. 7.2)		N/A
14.12	**Continued validity of previous design documentation assessed under a documented modification/change procedure**		N/A
	Software Classification for Software changes applied in accordance with Clause 4.3 and 4.4 of IEC 62304:2006 and IEC 62304:2006/ amd1:2015 .....:		N/A
	Software Process for Software changes applied according to Clause 5 of IEC 62304:2006 and IEC 62304:2006/ amd1:2015 .....:		N/A
	risk management for Software changes applied according to Clause 7 of IEC 62304:2006 and IEC 62304:2006/ amd1:2015.....:		N/A
	Configuration management of software changes applied per Clause 8 of IEC 62304:2006 and IEC 62304:2006/ amd1:2015 .....:		N/A
	Problem resolution for Software changes applied according to Clause 9 of IEC 62304:2006 and IEC 62304:2006/ amd1:2015 .....:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
14.13	**For pems incorporated into an it-network not validated by the pems manufacturer, instructions made available for implementing the connection include the following** .....:		N/A
	a) Purpose of the pems connection to an it-network		N/A
	b) required characteristics of the it-network		N/A
	c) required configuration of the it-network		N/A
	d) technical specifications of the network connection, including security specifications		N/A
	e) intended information flow between the pems, the it-network and other devices on the it-network, and the intended routing through the it-network		N/A
	f) a list of hazardous situations resulting from failure of the it-network to provide the required characteristics(ISO 14971 Cl. 5.2-5.5, 6, 7.1, 7.2)		N/A
	accompanying documents for the responsible organization include the following:		N/A
	– statement that connection to it-networks including other equipment could result in previously unidentified risks to patients, operators or third parties		N/A
	– Notification that the responsible organization identify, analyse, evaluate and control these risks		N/A
	– Notification that changes to the it-network could introduce new risks that require additional analysis		N/A
	- Changes to the it-network include: **- changes in network configuration** **- connection of additional items** **- disconnection of items** **- update of equipment** **- upgrade of equipment**		N/A
15	**CONSTRUCTION OF ME EQUIPMENT**		Pass
15.1	**Risks associated with arrangement of controls and indicators of me equipment addressed through the application of a usability engineering process** .....:	Component; to be evaluated in end product	N/A
15.2	**Parts of me equipment subject to mechanical wear, electrical, environmental degradation or ageing resulting in unacceptable risk when unchecked for a long period, are accessible for inspection, replacement, and maintenance**		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Inspection, servicing, replacement, and adjustment of parts of me equipment can easily be done without damage to or interference with adjacent parts or wiring		N/A
15.3	**Mechanical strength**		Pass
15.3.1	**Mould stress relief, push, impact, drop, and rough handling tests did not result in loss of basic safety or essential performance**		Pass
15.3.2	**Push test conducted** .....:	See Appended Table 15.3	Pass
	No damage resulting in an unacceptable risk sustained		Pass
15.3.3	**Impact test conducted** .....:	See Appended Table 15.3	Pass
	No damage resulting in an unacceptable risk sustained		Pass
15.3.4	**Drop test**		Pass
15.3.4.1	**Sample of hand-held me equipment, accessories and hand-held part with safe working load tested**.....:		N/A
	No unacceptable risk resulted		N/A
15.3.4.2	**Sample of portable me equipment, accessories and portable part with safe working load withstood stress as demonstrated by test** .....:	See Appended Table 15.3	Pass
	No damage resulting in an unacceptable risk sustained		Pass
15.3.5	**mobile me equipment and mobile part with safe working load and in most adverse condition in normal use passed Rough Handling tests**.....:		N/A
	No damage resulting in an unacceptable risk sustained		N/A
15.3.6	**Examination of enclosure made from moulded or formed thermoplastic material indicated that material distortion due to release of internal stresses by moulding or forming operations will not result in an unacceptable risk**		Pass
	Mould-stress relief test conducted by placing one sample of complete me equipment, enclosure or a portion of larger enclosure, for 7 hours in a circulating air oven at 10°C over the max temperature measured on enclosure in 11.1.3, but no less than 70 °C .....:	See Appended Table 15.3	Pass
	No damage resulting in an unacceptable risk		Pass
15.3.7	**Intended use, expected service life, and conditions for transport and storage were taken into consideration for selection and treatment of materials used in construction of me equipment**	Component, to be evaluated in end product	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Based on review of equipment, accompanying documents, specifications and processing of materials, and manufacturer's relevant tests or calculations, corrosion, ageing, mechanical wear, degradation of biological materials due to bacteria, plants, animals and the like, will not result in an unacceptable risk		N/A
15.4	**Me equipment components and general assembly**		Pass
15.4.1	**Incorrect connection of accessible connectors, removable without a tool, prevented where an unacceptable risk exists,:(ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)**	No such parts provided	N/A
	a) Plugs for connection of patient leads or patient cables cannot be connected to outlets on same me equipment intended for other functions,.....:		N/A
	b) Medical gas connections on me equipment for different gases to be operated in normal use are not interchangeable inspection.....:		N/A
15.4.2	**Temperature and overload control devices**		N/A
15.4.2.1	**a) Thermal cut-outs and over-current releases with automatic resetting not used in me equipment when their use could lead to a hazardous situation:(ISO 14971 Cl. 5.2-5.5, 6)**		N/A
	b) Thermal cut-outs with a safety function with reset by a soldering not fitted in me equipment		N/A
	c) An additional independent non-self-resetting thermal cut-out is provided:(ISO 14971 Cl. 5.2-5.5)		N/A
	d) Operation of thermal cut-out or over current release doesn't result in a hazardous situation or loss of essential performance :(ISO 14971 Cl. 5.2-5.5)		N/A
	e) Capacitors or other spark-suppression devices not connected between contacts of thermal cut-outs		N/A
	f) Use of thermal cut-outs or over-current releases do not affect safety as verified by following tests		N/A
	- Positive temperature coefficient devices) complied with IEC 60730-1: 2010, Clauses 15, 17, J.15, and J.17		N/A
	- Me equipment containing thermal cut-outs and over-current releases operated under the conditions of Clause 13 .....:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	- Self-resetting thermal cut-outs and over-current releases including circuits performing equivalent functions Certified according to appropriate standards.....:		N/A
	- In the absence of Certification in accordance with IEC standards, self-resetting thermal cut-outs and over-current releases including circuits performing equivalent functions operated 200 times		N/A
	Manual reset thermal cut-outs and over-current releases Certified in accordance with appropriate IEC standards		N/A
	manual reset thermal cut-outs and over-current releases operated 10 times		N/A
	Thermal protective devices tested separately from me equipment when engineering judgment indicated test results would not be impacted		N/A
	g) Protective device incorporating a fluid filled container with heating means, operated when heater switched on with container empty and prevented an unacceptable risk due to overheating		N/A
	h) Me equipment with tubular heating elements provided with protection against overheating:(ISO 14971 Cl. 5.2-5.5)		N/A
15.4.2.2	**Temperature settings clearly indicated when means provided to vary setting of thermostats**		N/A
15.4.3	**Batteries**		N/A
15.4.3.1	**Battery housings provided with ventilation: (ISO 14971 Cl. 5.2-5.5)**	No battery provided	N/A
	Battery compartments designed to prevent accidental short circuiting		N/A
15.4.3.2	**Means provided to prevent incorrect connection of polarity**		N/A
	risk management file includes an assessment of risks associated with incorrect connection or replacement of batteries:(ISO 14971 Cl. 5.2-5.5)		N/A
15.4.3.3	**Overcharging of battery prevented by virtue of design** .....:		N/A
	risk management file includes an assessment of risks associated with overcharging of batteries:(ISO 14971 Cl. 5.2-5.5)		N/A
15.4.3.4	**Primary lithium batteries comply with IEC 60086-4**		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Secondary lithium batteries comply with IEC 62133 or IEC 62133-2		N/A
15.4.3.5	**A properly rated protective device provided within internal electrical power source to protect against fire** .....:		N/A
	Protective device has adequate breaking capacity		N/A
	Justification for over-current releases or fuse exclusion is documented		N/A
	Short circuit test between the positive and negative poles of an internal electrical power source between the output and protective device(s) omitted where 2 moops provided, or		N/A
	Short circuit between the positive and negative poles of an internal electrical power source between the output and protective device(s) does not result in any hazardous situation		N/A
15.4.4	**Indicator lights provided to indicate me equipment is ready for** .....:	Green LED light is provided to indicate that it is ready for normal use	Pass
	An additional indicator light provided on me equipment with a stand-by state or a warm-up state exceeding 15 s,		N/A
	Indicator lights provided on me equipment incorporating non-luminous heaters to indicate heaters are operational		N/A
	risk management file includes an assessment of risks associated with the use of indicator lights for equipment incorporating non-luminous heaters:(ISO 14971 Cl. 5.2-5.5)		N/A
	Requirement not applied to heated stylus-pens for recording purposes		N/A
	Indicator lights provided on me equipment to indicate an output exists		N/A
	Colours of indicator lights complied with 7.8.1	Green LED light is provided to indicate that it is ready for normal use	Pass
	Charging mode visibly indicated		N/A
15.4.5	**Risks associated with pre-set controls addressed in risk management process: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)**	No pre-set controls provided	N/A
15.4.6	**Actuating parts of controls of me equipment**		N/A
15.4.6.1	**a) Actuating parts cannot be pulled off or loosened during normal use**	No such parts provided	N/A

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Clause	Requirement + Test	Result - Remark	Verdict

	b) Controls secured so that the indication of any scale always corresponds to the position of the control		N/A
	c) Incorrect connection prevented by adequate construction when it could be separated without use of a tool		N/A
	When torque values per Table 30 applied knobs did not rotate :.		N/A
	Tests conducted with no unacceptable risk.....:		N/A
15.4.6.2	**Stops on rotating/ movable parts of controls are of adequate mechanical strength**.....:	No such parts provided	N/A
	Torque values in Table 30 applied.....:		N/A
	No unexpected change of the controlled parameter when tested .....:		N/A
15.4.7	**Cord-connected hand-held and foot-operated control devices**		N/A
15.4.7.1	**a) Hand-held control devices of me equipment complied with 15.3.4.1**		N/A
	b) Foot-operated control device supported an actuating force of 1350 N in its position of normal use with no damage .....:		N/A
15.4.7.2	**Control device of hand-held and foot-operated control devices turned in all possible abnormal positions and placed on a flat surface** .....:		N/A
	No unacceptable risk caused by changing control setting when accidentally placed in an abnormal position		N/A
15.4.7.3	**a) Foot-operated control device is at least rated IPX1** .....:		N/A
	b) Enclosure of foot operated control devices containing electrical circuits is at least IPX6.....:		N/A
15.4.8	**Aluminium wires less than 16 mm2 in cross-sectional area are not used**		N/A
15.4.9	**a) Oil container in portable me equipment allows for expansion of oil and is adequately sealed**		N/A
	b) Oil containers in mobile me equipment sealed to prevent loss of oil during transport		N/A
	A pressure-release device operating during normal use is provided		N/A
	c) Partially sealed oil-filled me equipment and its parts provided with means for checking the oil level to detect leakage		N/A
	Me equipment and technical description examined, and manual tests conducted to confirm compliance with above requirements		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

15.5	**Mains supply transformers of me equipment and transformers providing separation in accordance with 8.5**		Pass
15.5.1	**Overheating**		Pass
15.5.1.1	**Transformers of me equipment are protected against overheating**.....:	See appended Tables 15.5.1.2 and 15.5.1.3	Pass
	During tests, windings did not open, no hazardous situation occurred, and maximum temperatures of windings did not exceed values in Table 31		Pass
	Dielectric strength test conducted after short circuit and overload tests.....:	See appended Table 15.5.2	Pass
15.5.1.2	**Transformer output winding short circuited, and test continued until protective device operated or thermal stability achieved**.....:	See appended Table 15.5.1.2	Pass
	Short circuit applied directly across output windings		Pass
15.5.1.3	**Multiple overload tests conducted on windings**:	See appended Table 15.5.1.3	Pass
15.5.2	**Transformers operating at a frequency above 1kHz tested according to clause 8.8.3**.....:	See appended Table 8.8.3	Pass
	Transformer windings provided with adequate insulation		Pass
	Dielectric strength tests were conducted.....:		N/A
15.5.3	**Transformers forming means of protection as required by 8.5 comply with**.....:	See appended Table 8.10	Pass
	- Means provided to prevent displacement of end turns		Pass
	- protective earth screens with a single turn have insulated overlap		N/A
	- Exit of wires form internal windings of toroid transformers protected with double sleeving		N/A
	- insulation between primary and secondary windings complies with 8.8.2		Pass
	- creepage distances and air clearance comply with 8.9.4		Pass
16	**ME SYSTEMS**		N/A
16.1	**After installation or subsequent modification, Me system didn't result in an unacceptable risk**	Component; to be evaluated in end product	N/A
	risk management file includes an assessment of risks associated with installation and modification of an me system:(ISO 14971 Cl. 5.2-5.5, 6)		N/A
	Only hazards arising from combining various equipment to form a me system considered		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– me system provides the level of safety within the patient environment equivalent to me equipment complying with this standard		N/A
	– me system provides the level of safety outside patient environment equivalent to equipment complying with their respective IEC or ISO safety standards		N/A
	– tests performed in normal condition, except as specified		N/A
	– tests performed under operating conditions specified by manufacturer of me system		N/A
	Safety tests previously conducted on individual equipment of me system according to relevant standards not repeated		N/A
	Risk management methods used by manufacturer of an me system reconfigurable by responsible organization or operator		N/A
	Non-me equipment used in me system complied with applicable IEC or ISO safety standards		N/A
	Equipment relying only on basic insulation for protection against electric shock not used in me system		N/A
16.2	**Accompanying documents of an me system**		N/A
	Documents containing all data necessary for me system to be used as intended by manufacturer including a contact address accompany me system or modified me system		N/A
	Accompanying documents regarded as a part of me system		N/A
	a) accompanying documents provided for each item of me equipment supplied by manufacturer		N/A
	b) accompanying documents provided for each item of non-me equipment supplied by manufacturer		N/A
	c) the required information is provided .....:		N/A
	– specifications, instructions for use as intended by manufacturer, and a list of all items forming the me system		N/A
	– instructions for installation, assembly, and modification of me system to ensure continued compliance with this standard		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– instructions for cleaning and, when applicable, disinfecting and sterilizing each item of equipment or equipment part forming part of the me system		N/A
	– additional safety measures to be applied during installation of me system		N/A
	– identification of parts of me system suitable for use within the patient environment		N/A
	– additional measures to be applied during preventive maintenance		N/A
	– a warning forbidding placement of multiple socket-outlet, when provided and it is a separate item, on the floor		N/A
	– a warning indicating an additional multiple socket-outlet or extension cord not to be connected to me system		N/A
	– a warning to connect only items that have been specified as part of me system or specified as being compatible with me system		N/A
	– maximum permissible load for any multiple socket-outlet(s) used with me system		N/A
	– instructions indicating multiple socket-outlets provided with the me system to be used only for supplying power to equipment intended to form part of me system		N/A
	– an explanation indicating risks of connecting non-me equipment supplied as a part of me system directly to wall outlet when non-me equipment is intended to be supplied via a multiple socket-outlet with a separating transformer		N/A
	– an explanation indicating risks of connecting any equipment supplied as a part of me system to multiple socket-outlet		N/A
	– permissible environmental conditions of use for me system including conditions for transport and storage		N/A
	– instructions to operator not to, simultaneously, touch parts referred to in 16.4 and patient		N/A
	d) the following instructions provided for use by responsible organization.....:		N/A
	– adjustment, cleaning, sterilization, and disinfection procedures		N/A
	– assembly of me systems and modifications during actual service life evaluated based on the requirements of this standard		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
16.3	**Instructions for use of me equipment intended to receive its power from other equipment in an me system, describe the other equipment to ensure compliance with these requirements**		N/A
	Transient currents restricted to allowable levels for the specified IPS or UPS.....:		N/A
	Technical description and installation instructions specify the actual transient currents where an IPS or UPS is not specified		N/A
16.4	**Parts of non-me equipment in patient environment subject to contact by operator during maintenance, calibration, after removal of covers, connectors operated at a voltage ≤ voltage in 8.4.2 c)**		N/A
16.5	**Safety measures incorporating a separation device applied when functional connection between me equipment and other items of an me system or other systems can cause allowable values of leakage current to exceed**		N/A
	Separation device has dielectric strength, creepage and clearances required for one means of operator protection		N/A
	Working voltage was highest voltage across separation device during a fault condition, but not less than maximum mains voltage (V).....:		N/A
16.6	**Leakage currents**		N/A
16.6.1	**Touch current in normal condition did not exceed 100µA**.....:		N/A
	Touch current did not exceed 500µA in event of interruption of any non-permanently installed protective earth conductor.....:		N/A
16.6.2	**Current in protective earth conductor of multiple socket-outlet didn't exceed 5 mA**.....:		N/A
16.6.3	**Patient leakage current and total patient leakage current of me system in normal condition did not exceed values**.....:		N/A
16.7	**Me system complied with applicable requirements of Clause 9**.....:		N/A
16.8	**Interruption and restoration power to the me system or any part of the me system did not result in a loss of basic safety or essential performance**		N/A
16.9	**Me system connections and wiring**		N/A
16.9.1	**Incorrect connection of accessible connectors, removable without a tool, prevented where unacceptable RISK can result**.....:	Component; to be evaluated in end product	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	risk management file includes an assessment of risks associated with plugs for connection of patient leads or cables likely to be located in the patient environment:(ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)		N/A
	– Plugs for connection of patient leads or patient cables could not be connected to other outlets of the same me system likely to be located in patient environment, except when examination of connectors and interchanging them proved no unacceptable risk results		N/A
	Medical gas connections on the me system for different gasses operated in normal use are not interchangeable		N/A
16.9.2	**Mains parts, components and layout**		N/A
16.9.2.1	**a) – multiple socket-outlet only allows connection using a tool, or**		N/A
	– multiple socket-outlet is of a type that cannot accept mains plugs of any of the kinds specified in IEC/TR 60083, or		N/A
	– multiple socket-outlet is supplied via a separating transformer		N/A
	b) – multiple socket-outlet marked with SAFETY SIGN 2 of Table D.2 visible in normal use, and		N/A
	– marked either individually or in combinations, with the maximum allowed continuous output in amperes or volt-amperes, or		N/A
	– marked to indicate the equipment or equipment parts it may safely be attached to		N/A
	– multiple socket-outlet is a separate item or an integral part of me equipment or non-me equipment		N/A
	c) Multiple socket-outlet complied with IEC 60884-1 and the following requirements.....:		N/A
	– Creepage and clearances complied with 8.9		N/A
	– It is class i, and protective earth conductor is connected to earthing contacts in socket-outlets		N/A
	– Protective earth terminals and protective earth connections comply with 8.6.....:		N/A
	– Enclosure complied with 8.4.2 d)		N/A
	– Mains terminal devices and wiring complied with 8.11.4, when applicable		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– Ratings of components are not in conflict with conditions of use.....:		N/A
	– Electrical terminals and connectors of multiple socket-outlets prevent incorrect connection of accessible connectors removable without a tool		N/A
	– Power supply cord complied with 8.11.3		N/A
	d) Additional requirements applied when multiple socket-outlet combined with a separating transformer .....:		N/A
	– Separating transformer complied with this standard or IEC 61558-2-1, ...:		N/A
	– Separating transformer is class i		N/A
	– Degree of protection against ingress of water specified as in IEC 60529		N/A
	– Separating transformer assembly marked according to 7.2 and 7.3		N/A
	– Multiple socket-outlet permanently connected to separating transformer, or socket-outlet of separating transformer assembly cannot accept mains plugs as identified in IEC/TR 60083		N/A
16.9.2.2	**The impedance between the protective earth pin in the mains plug and any part that is protectively earthed and protected by only the supply mains circuit over-current release, did not exceed 200 mΩ**		N/A
	The impedance of an earth pathway protected by an additional intermediate circuit breaker or fuse rated 13A or lower, did not exceed 400 mΩ		N/A
	Removal of any single item of equipment in me system will not interrupt the protective earthing of any other part without simultaneous disconnection of electrical supply to that part		N/A
	Additional protective earth conductors can be detachable only by use of a tool		N/A
16.9.2.3	**Conductors connecting different items within an me system protected against mechanical damage**		N/A
17	**ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS**		N/E
	Risks associated confirmed by review .....:	Component; to be evaluated in end product	N/E

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Clause	Requirement + Test	Result - Remark	Verdict
	risk management file includes an assessment of risks associated with the introduction of electromagnetic phenomena into the environment by the equipment or system:(ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)		N/E
ANNEX G	**PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES**		N/A
G.2	**Locations and basic requirements**		N/A
G.2.1	**Parts of category apg me equipment in which a flammable anaesthetic mixture with air occurs are category ap or apg me equipment and complied with G.3, G.4, and G.5**	Not evaluated for use in the presence of Flammable Anesthetic Mixtures.	N/A
G.2.2	**Flammable aesthetic mixture with**		N/A
G.2.3	**A flammable aesthetic mixture with oxygen or nitrous oxide**		N/A
G.2.4	**Me equipment specified for use with flammable aesthetic mixture with air complied with G.4 and G.5**		N/A
G.2.5	**Me equipment or parts thereof for use with flammable aesthetic mixture with oxygen or nitrous oxide comply with G.4 and G.6**		N/A
	Me equipment in G.2.4 to G.2.5 met appropriate tests of G.3-G.6 conducted after tests of 11.6.6 and 11.6.7		N/A
G.3	**Marking, accompanying documents**		N/A
G.3.1	**Category apg me equipment prominently marked "apg" (symbol 23 in Table D.1)** .....:		N/A
	Length of green-coloured band is ≥ 4 cm, and size of marking is as large as possible for particular case		N/A
	When above marking not possible, relevant information included in instructions for use .....:		N/A
	Marking complied with tests and criteria of 7.1.2 and 7.1.3		N/A
G.3.2	**Category ap me equipment prominently marked, with a green-coloured circle "ap" (symbol 22 in Table D.1)** .....:		N/A
	Marking is as large as possible for the particular case		N/A
	When above marking not possible, the relevant information included in instructions for use .....:		N/A
	Marking complied with tests and criteria of 7.1.2 and 7.1.3		N/A
G.3.3	**The marking placed on major part of me equipment for category ap or apg parts**		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
G.3.4	**Accompanying documents contain an indication enabling the responsible organization to distinguish between category ap and apg parts**		N/A
G.3.5	**Marking clearly indicates which parts are category ap or apg when only certain me equipment parts are category ap or apg**		N/A
G.4	**Common requirements for category ap and category apg me equipment**		N/A
G.4.1	**a) Creepage and clearances are according to Table 12 for one means of patient protection**		N/A
	b) Connections protected against accidental disconnection		N/A
	c) Category ap and apg not provided with a detachable power supply cord,		N/A
G.4.2	**Construction details**		N/A
	a) Opening of an enclosure protecting against penetration of gases or vapours into me equipment or its parts possible only with a tool		N/A
	b) Enclosure complies with .....:		N/A
	– no openings on top covers of enclosure,		N/A
	– openings in side-covers prevented penetration of a solid cylindrical test rod		N/A
	– openings in base plates prevented penetration of a solid cylindrical test		N/A
	c) Short circuiting conductor(s) to a conductive part (when no explosive gasses) did not result in loss of integrity of the part, an unacceptable temperature, or any hazardous situation		N/A
G.4.3	**a) Electrostatic charges prevented on category ap and apg me equipment by a combination of appropriate measures**		N/A
	– Use of antistatic materials with a limited electrical resistance .....:		N/A
	– Provision of electrically conductive paths from me equipment or its parts to a conductive floor, protective earth or potential equalization system, or via wheels to an antistatic floor		N/A
	b) Electrical resistance limits of aesthetic tubing, mattresses/ pads, castor tires & other antistatic material comply with ISO 2882.....:		N/A
G.4.4	**Corona cannot be produced by components or parts of me equipment operating at more than 2000 V a.c. or 2400 V d.c. and not included in enclosures complying with G.5.4 or G.5.5**		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

G.5	**Requirements and tests for category ap me equipment, parts and components**		N/A
G.5.1	**Me equipment, its parts or components do not ignite flammable aesthetic mixtures with air under normal use and conditions based on compliance with G.5.2 to G.5.5**	Not evaluated for use in the presence of Flammable Anesthetic Mixtures.	N/A
	Alternatively, me equipment, its parts, and components complied with requirements of IEC 60079-0 for pressurized enclosures (IEC 60079-2); for sand-filled enclosures, IEC 60079-5; or for oil immersed equipment, IEC 60079-6; and with this standard excluding G.5.2 to G.5.5:		N/A
G.5.2	**Temperature limits** .....:		N/A
G.5.3	**Me equipment, its parts, and components producing sparks in normal use and condition complied with temperature requirements of G.5.2, and Umax and Imax occurring in their circuits, and complied as follows** .....:		N/A
	Measured Umax ≤ UzR with IzR as in Fig. G.1 ...:		N/A
	Measured Umax ≤ Uc with Cmax as in Fig. G.2.:		N/A
	Measured Imax ≤ IzR with UzR as in Fig G.1 .....:		N/A
	Measured Imax ≤ IzL with Lmax and a Umax ≤ 24 V as in Fig G.3.....:		N/A
	– Combinations of currents and corresponding voltages within the limitations IzR.UzR ≤ 50 W extrapolated from Fig G.1		N/A
	No extrapolation made for voltages above 42 V		N/A
	– Combinations of capacitances and corresponding voltages within limitations of C/2U2 ≤ 1.2 mJ extrapolated from Fig G.2		N/A
	No extrapolation made for voltages above 242V		N/A
	Umax determined using actual resistance R		N/A
	– Combinations of currents and corresponding inductances within limitations L/2I2 ≤ 0.3 mJ extrapolated from Fig G.3		N/A
	No extrapolation made for inductances larger than 900 mH		N/A
	– Umax was the highest supply voltage occurring in circuit under investigation with sparking contact open		N/A
	– Imax was the highest current flowing in circuit under investigation with sparking contact closed		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– Cmax and Lmax taken as values occurring at the component under investigation producing sparks		N/A
	– Peak value considered when a.c. supplied		N/A
	– An equivalent circuit calculated to determine equivalent max capacitance, inductance, and equivalent Umax and Imax, either as d.c. or a.c. peak values in case of a complicated circuit.....:		N/A
	Temperature measurements made according to 11.1, and Umax, Imax, R, Lmax , and Cmax determined with application of Figs G.1-G.3 .....:		N/A
	Alternatively, compliance was verified by examination of design data .....:		N/A
G.5.4	**External ventilation with internal overpressure**		N/A
	Me equipment, its parts, and components enclosed in an enclosure with external ventilation by means of internal overpressure complied with the following requirements .....:		N/A
	a) Flammable aesthetic mixtures with air t removed by ventilation before equipment energized,		N/A
	b) Overpressure inside enclosure was 75 Pa, min., in normal condition (Pa) .....:		N/A
	Overpressure maintained at the site of potential ignition		N/A
	Me equipment could be energized only after the required minimum overpressure was present long enough to ventilate the enclosure		N/A
	Me equipment energized at will or repeatedly when overpressure was continuously present		N/A
	c) Ignition sources de-energized automatically when during operation overpressure dropped below 50 Pa (Pa) .....:		N/A
	d) External surface of enclosure did not exceed 150 °C in 25 °C .....:		N/A
G.5.5	**Enclosures with restricted breathing**		N/A
	Me equipment, its parts, and components enclosed in an enclosure with restricted breathing complied with the following.....:		N/A
	a) A flammable aesthetic mixture with air did not form inside enclosure with restricted breathing		N/A
	b) Gasket or sealing material used to maintain tightness complied with aging test B-b of IEC 60068-2-2, Clause 15, at 70 °C ± 2 °C and 96 h ..:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	c) Gas-tightness of enclosure containing inlets for flexible cords maintained		N/A
	Cords are fitted with adequate anchorages to limit stresses as determined by test		N/A
	Overpressure not reduced below 200 Pa		N/A
	Tests waived when examination of enclosure indicated it is completely sealed or gas-tight without a doubt (100 % degree of certainty)		N/A
	Operating temperature of external surface of enclosure was ≤ 150 °C in 25 °C (°C) .....:		N/A
	Steady state operating temperature of enclosure also measured (°C) .....:		N/A
G.6	**category apg me equipment, parts and components thereof**		N/A
G.6.1	**Me equipment, its parts, and components did not ignite flammable aesthetic mixture with oxygen or nitrous oxide under normal use and single fault condition**	Not evaluated for use in the presence of Flammable Anesthetic Mixtures.	N/A
	Me equipment, its parts, and components not complying with G.6.3 subjected to a continuous operation test		N/A
G.6.2	**Parts and components of category apg me equipment operating in a flammable aesthetic mixture with oxygen or nitrous oxide supplied from a source isolated from earth by insulation equal to one means of patient protection and from electrical parts by insulation twice the means of patient protection** .....:		N/A
G.6.3	**Test of G.6.1 waived when the following requirements were met in normal use and under normal and single fault conditions**.....:		N/A
	a) no sparks produced and temperatures did not exceed 90 °C, or		N/A
	b) a temperature limit of 90 °C not exceeded, sparks produced in normal use, and single fault conditions, except Umax and Imax occurring in their circuits complied with requirements, taking Cmax and Lmax into consideration .....:		N/A
	Measured Umax ≤ UzR with IzR as in Fig. G.4...:		N/A
	Measured Umax ≤ Uzc with Cmax as in Fig. G.5 .....:		N/A
	Measured Imax ≤ IzR with UzR as in Fig G.4 .....:		N/A
	Measured Imax ≤ IzL with Lmax and a Umax ≤ 24 V as in Fig G.6.....:		N/A
	– Extrapolation from Figs G.4, G.5, and G.6 was limited to areas indicated		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– Umax was the highest no-load voltage occurring in the circuit under investigation, taking into consideration mains voltage variations as in Cl. 4.10		N/A
	– Imax was the highest current flowing in the circuit under investigation, considering mains voltage variations as in Cl. 4.10		N/A
	– Cmax and Lmax are values occurring in relevant circuit		N/A
	– Umax additionally determined with actual resistance R when equivalent resistance R in Fig G.5 was less than 8000 Ω		N/A
	– Peak value considered when a.c. supplied		N/A
	– An equivalent circuit calculated to determine max capacitance, inductance, and Umax and Imax, either as d.c. or a.c. peak values in case of a complicated circuit .....:		N/A
	– When energy produced in an inductance or capacitance in a circuit is limited by voltage or current-limiting devices, two independent components applied, to obtain the required limitation even when a first fault (short or open circuit) in one of these components		N/A
	- requirement not applied to transformers complying with this standard		N/A
	- requirement not applied to wire-wound current-limiting resistors provided with a protection against unwinding of the wire in case of rupture		N/A
	Compliance verified by examination of category apg me equipment, parts, and components , or		N/A
	Temperature measurements made in accordance with 11.1 .....:		N/A
	- or Umax, Imax, R, Lmax and Cmax determined together with application of Figs G.4-G.6 .....:		N/A
	Alternatively, compliance verified by comparison with design data .....:		N/A
G.6.4	**Me equipment, its parts, and components heating a flammable aesthetic mixture with oxygen or nitrous oxide provided with a non-self-resetting thermal cut-out and complied with 15.4.2.1**.....:		N/A
	Current-carrying part of heating element is not in direct contact with flammable aesthetic mixture with oxygen or nitrous oxide		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

G.7	**Test apparatus for flammable mixtures according to this Clause and Fig G.7**		N/A
ANNEX L	**INSULATED WINDING WIRES FOR USE WITHOUT INTERLEAVED INSULATION**		Pass
L.1	**Basic, supplementary, double, and reinforced insulation in wound components without interleaved insulation complied with this Annex**	UL recognized TIW with VDE certificate for Annex L compliance.	Pass
L.2	**Wire construction**		N/A
	Overlap of layers when wire is insulated with two or more spirally wrapped layers of tape is adequate to ensure continued overlap during manufacture of wound component		N/A
	Layers of spirally wrapped wire insulation are sufficiently secured to maintain the overlap		N/A
L.3	**Type Test**		N/A
	The wire subjected to tests of L.3.1 to L.3.4 at a temperature and a relative humidity specified		N/A
	Temperature (°C) .....:		-
	Humidity (%).....:		-
L.3.1	**Dielectric strength**		N/A
	Dielectric strength test of Clause 8.8.3 for the appropriate type and number of mop(s) conducted with no breakdown.....:		N/A
	– 3000 V for basic and supplementary insulation (V).....:		N/A
	– 6000 V for reinforced insulation (V).....:		N/A
L.3.2	**Flexibility and adherence**		N/A
	Sample subjected to flexibility and adherence		N/A
	Sample examined per IEC 60851-3: 1997, cl. 5.1.1.4, followed by dielectric test of cl. 8.8.3, with no breakdown		N/A
	Test voltage was at least the voltage in Tables 6 and 7 but not less than the following .....:		N/A
	– 1500 V for basic and supplementary insulation (V).....:		N/A
	– 3000 V for reinforced insulation (V).....:		N/A
	Tension applied to wire during winding on mandrel calculated from the wire diameter equivalent to 118 MPa ± 11.8 MPa.....:		N/A
L.3.3	**Heat Shock**		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Sample subjected to heat shock test 9 of IEC 60851-6:1996, followed by dielectric strength test of clause 8.8.3		N/A
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following .....:		N/A
	– 1500 V for basic and supplementary insulation (V) .....:		N/A
	– 3000 V for reinforced insulation (V) .....:		N/A
	Oven temperature based on Table L.2 (°C) .....:		-
	Mandrel diameter and tension applied as in clause L.3.2, (MPa; N/mm2) .....:		N/A
	Dielectric strength test conducted at room temperature after removal from the oven		N/A
L.3.4	**Retention of electric strength after bending**		N/A
	Five samples prepared as in L.3.2 subjected to dielectric strength and bending tests		N/A
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following .....:		N/A
	– 1500 V for basic and supplementary insulation (V) .....:		N/A
	– 3000 V for reinforced insulation (V) .....:		N/A
	Test voltage applied between the shot and conductor		N/A
	Mandrel diameter and tension applied as in L.3.2, (MPa; N/mm2) .....:		N/A
L.4	**Tests during manufacture**		N/A
L.4.1	**Production line dielectric strength tests done by the manufacture per L.4.2 and L.4.3** .....:		N/A
L.4.2	**Test voltage for routine testing (100 % testing) is at least the voltage in Tables 6 and 7 but not less than the following** .....:		N/A
	– 1500 V r.m.s. or 2100 V peak for basic and supplementary insulation (V) .....:		N/A
	– 3000 V r.m.s. or 4200 V peak for reinforced insulation (V) .....:		N/A
L.4.3	**Sampling tests conducted using twisted pair samples (IEC 60851-5:1996, clause 4.4.1)** .....:		N/A
	Minimum breakdown test voltage at least twice the voltage in Tables 6 and 7 but not less than.:		N/A
	– 3000 V r.m.s. or 4200 V peak for basic and supplementary insulation .....:		N/A
	– 6000 V r.m.s. or 8400 V peak for reinforced insulation .....:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

4.2.2	RM RESULTS TABLE: General requirements for RISK MANAGEMENT			Pass
Clause of ISO 14971	**Document Ref. in RMF (Document No. paragraph/clause, version)**		**Result - Remarks**	**Verdict**
	General process	**Particular Medical Device**		
4.1	Risk management procedure, document No. GTQPR05000, version A.2, chapter 6.0	-	Risk Management Process (excluding production and post-production)	Pass
4.2	Risk management procedure, document No. GTQPR05000, version A.2, chapter 4.0	-	Adequate Resources	Pass
4.2	Risk management procedure, document No. GTQPR05000, version A.2, chapter 4.0	-	Assignment of qualified personnel	Pass
4.2	Risk management procedure, document No. GTQPR05000, version A.2, chapter 5.0	-	Policy for determining criteria for risk acceptability	Pass
4.3	-	Risk management procedure, document No. GTQPR05000, version A.2, chapter 4.0	Competence of personnel	Pass
4.4a	-	Risk management plan, document No. GT-RMPLAN2013-010, version A.2, chapter 1.1	Risk Management Plan - the scope of the planned risk management activities	Pass
4.4b	-	Risk management plan, document No. GT-RMPLAN2013-010, version A.2, chapter 1.2	Risk Management Plan - assignment of responsibilities and authorities	Pass
4.4c	-	Risk management plan, document No. GT-RMPLAN2013-010, version A.2, chapter 1.2	Risk Management Plan - requirements for review of risk management activities	Pass
4.4d	-	Risk management plan, document No. GT-RMPLAN2013-010, version A.2, chapter 1.3	Risk Management Plan - criteria for risk acceptability	Pass
4.4e	-	Risk management plan, document No. GT-RMPLAN2013-010, version A.2, chapter 1.5	Risk Management Plan - a method to evaluate the overall residual risk, and criteria for acceptability of the overall residual risk	Pass
4.4f	-	Risk management plan, document No. GT-RMPLAN2013-010, version A.2, chapter 1.5	Risk Management Plan - activities for verification of the implementation and effectiveness of risk control measures	Pass
4.5	-	Risk management plan, document No. GT-RMPLAN2013-010, version A.2,	Risk Management File	Pass

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Clause	Requirement + Test		Result - Remark	Verdict
		and risk management report, doc. No. GT-RM2013-010, version A.2		
5.1	-	Risk management report, doc. No. GT-RM2013-010, version A.2, chapter 6	Risk Analysis - Process	Pass
5.2	-	Risk management report, doc. No. GT-RM2013-010, version A.2, chapter 6	Risk Analysis - Intended use and reasonably foreseeable misuse	Pass
5.3	-	Risk management report, doc. No. GT-RM2013-010, version A.2, chapter 6	Risk Analysis - Identification of characteristics related to safety	Pass
5.4	-	Risk management report, doc. No. GT-RM2013-010, version A.2, chapter 6.3	Risk Analysis - Identification of hazards and hazardous situations	Pass
5.5	-	Risk management report, doc. No. GT-RM2013-010, version A.2, chapter 6.4	Risk Analysis - Risk estimation	Pass
6	-	Risk management report, doc. No. GT-RM2013-010, version A.2, chapter 7	Risk Evaluation	Pass
7.1	-	Risk management report, doc. No. GT-RM2013-010, version A.2, chapter 6	Risk Control - Risk control option analysis	Pass
7.2	-	Risk management report, doc. No. GT-RM2013-010, version A.2, chapter 8.1	Risk Control - Implementation of risk control measures	Pass
7.3	-	Risk management report, doc. No. GT-RM2013-010, version A.2, chapter 8.2	Risk Control - Residual risk evaluation	Pass
7.4	-	Risk management report, doc. No. GT-RM2013-010, version A.2, chapter 8.3	Risk Control - Benefit-risk analysis	Pass
7.5a	-	-	No risks arising from risk control measures (new hazards or hazardous situations introduced)	N/A
7.5b	-	Risk management report, doc. No. GT-RM2013-010, version A.2, chapter 8.1	No risks arising from risk control measures (estimated risks for previously identified hazardous situations affected)	Pass
7.6	-	Risk management report, doc. No. GT-RM2013-010, version A.2, chapter 8.1	Risk Control - Completeness of risk control	Pass
8	-	Risk management report, doc. No. GT-RM2013-010, version A.2, chapter 8.2	Evaluation of overall residual risk	Pass
9	-	Risk management report, doc. No. GT-RM2013-010, version A.2	Risk management review	Pass
Supplementary Information: Document Ref should be with regards to the policy/procedure documents and documents containing Risk Management Process-specific output.				

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4.3	TABLE: ESSENTIAL PERFORMANCE		N/A
List of ESSENTIAL PERFORMANCE functions		**MANUFACTURER'S document number reference or reference from this standard or collateral or particular standard(s)**	**Remarks**
Supplementary Information: ESSENTIAL PERFORMANCE is performance, the absence or degradation of which, would result in an unacceptable risk.			

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4.11	TABLE: Power Input					P
Operating Conditions / Ratings		**Voltage (V)**	**Frequency (Hz)**	**Current (A)**	**Power (W or VA)**	**Power factor (cos φ)**
Model: GTM96600-6554-TP3 Output: 54V, 1.20A, 65.0W		85	50	1.343	114.155 VA / 71.68 W	0.623
Ditto		90	50	1.281	115.29	0.618
Ditto		100	50	1.171	117.1 VA	0.614
Ditto		240	50	0.56	134.4 VA	0.525
Ditto		264	50	0.511	134.904	0.525
Ditto		85	60	1.32	112.2 VA	0.655
Ditto		90	60	1.243	111.87	0.646
Ditto		100	60	1.123	112.3 VA	0.639
Ditto		240	60	0.548	131.52	0.537
Ditto		264	60	0.522	137.808	0.512
Model: GTM96600-4005-TP3 Output: 5.0V, 8.0A, 40.0W		85	50	0.919	78.115 VA / 47.47 W	0.608
Ditto		90	50	0.868	78.12 VA	0.607
Ditto		100	50	0.787	78.7 VA /	0.598
Ditto		240	50	0.386	92.64 VA	0.498
Ditto		264	60	0.359	94.776	0.488
Ditto		85	60	0.88	74.8 VA /	0.634
Ditto		90	60	0.837	75.33 VA	0.628
Ditto		100	60	0.76	76 VA /	0.619
Ditto		240	60	0.377	90.48 VA	0.510
Ditto		264	60	0.353	93.192	0.496
Supplementary Information:						

5.9.2	TABLE: Determination of ACCESSIBLE parts	P
Location	**Determination method (NOTE1)**	**Comments**
Plastic enclosure	Visual & test figure	Model GTM96600-6554-P2, accessible part
Output connector 1	Visual & test figure	Model GTM96600-6554-P2, accessible part
Output connector 2	Visual & test figure	Model GTM96600-6554-P2, accessible part
Output connector 3	Visual & test figure	Model GTM96600-6554-P2, accessible part
Supplementary information: 1) NOTE: The determination methods are: visual; rigid test finger; jointed test finger; test hook.		

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7.1.2	TABLE: Legibility of Marking		N/A
Markings tested		**Ambient Illuminance (lx)**	**Remarks**
Outside Markings (Clause 7.2).....:			
Inside Markings (Clause 7.3).....:			
Controls & Instruments (Clause 7.4).....:			
SAFETY SIGNS (Clause 7.5).....:			
Symbols (Clause 7.6).....:			
Supplementary information: Observer, with a visual acuity of 0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20) and is able to read N6 of the Jaeger test card in normal room lighting condition (~500lx), reads marking at ambient illuminance least favourable level in the range of 100 lx to 1,500 lx. The ME EQUIPMENT or its part was positioned so that the viewpoint was the intended position of the OPERATOR or if not defined at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of the marking and at a distance of 1 m.			

7.1.3	TABLE: Durability of marking test		P
Characteristics of the Marking Label tested:			**Remarks**
Material of Marking Label .....:			
Ink/other printing material or process .....:			
Material (composition) of Warning Label .....:			
Ink/other printing material or process .....:			
Other.....:			
Marking Label Tested:			**Remarks**
Supplementary information: Marking rubbed by hand, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with ethanol 96%, and then for 15 s with a cloth rag soaked with isopropyl alcohol. Same material used, tests had been conducted in E341350-D1007-1/A1/C0-UL, test results refer to E341350-D1007-1/A1/C0-UL.			

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8.4.2	TABLE: TABLE: Working Voltage / Power Measurement					P
Test supply voltage/frequency (V/Hz)[1)] ..... :						
Location From/To	Measured values					Remarks
	Vrms	Vpk or ~~Vdc~~	Peak-to-peak ripple[2)]	Power W/VA	Energy (J)	
GTM96600-6554-TP3 (F3 insulation construction) (+54Vdc/1.2A)	-	-	-	-	-	-
T1 pin 1 to pin A	206.7	370.0	392.5	-	-	
T1 pin 3 to pin A	205.3	355.6	364.3	-	-	
T1 pin 4 to pin A	183.9	344.4	364.9	-	-	
T1 pin 5 to pin A	183.3	337.7	352.9	-	-	
T1 pin 1 to pin B	209.1	387.0	423.0	-	-	Max. Vrms, Max. Vp
T1 pin 3 to pin B	205.4	343.0	342.3	-	-	
T1 pin 4 to pin B	183.4	329.1	337.2	-	-	
T1 pin 5 to pin B	183.7	334.4	345.0	-	-	
U4 pin 1 to pin 3	201.5	353.6	342.8	-	-	
U4 pin 2 to pin 3	199.3	350.0	341.5	-	-	
U4 pin 1 to pin 4	200.2	352.1	341.7	-	-	
U4 pin 2 to pin 4	198.2	349.1	342.5	-	-	
CY1 Pri. to CY2 Sec	182.5	328.8	337.1	-	-	
Between CY1	181.6	328.1	336.3	-	-	
Between CY2	4.14V	4.48	0.649	-	-	
GTM96600-4005-TP3 (F3 insulation construction) (+5Vdc/8A)	-	-	-	-	-	-
T1 pin 1 to pin 12	199.8	355.4	366.0	-	-	
T1 pin 3 to pin	199.6	350.0	347.6	-	-	

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Clause	Requirement + Test	Result - Remark	Verdict

8.4.2	TABLE: TABLE: Working Voltage / Power Measurement					P
12						
T1 pin 4 to pin 12	169.7	334.2	347.7	-	-	
T1 pin 5 to pin 12	170.1	332.7	337.2	-	-	
T1 pin 1 to pin A/7	199.4	356.0	399.6	-	-	
T1 pin 3 to pin A/7	196.5	344.7	344.2	-	-	
T1 pin 4 to pin A/7	169.0	329.0	338.5	-	-	
T1 pin 5 to pin A/7	169.6	336.1	341.9	-	-	
T1 pin 1 to pin B	198.4	357.0	405.0	-	-	
T1 pin 3 to pin B	196.0	340.8	340.6	-	-	
T1 pin 4 to pin B	169.0	328.5	335.5	-	-	
T1 pin 5 to pin B	169.5	341.1	348.2	-	-	
U4 pin 1 to pin 3	172.0	333.1	335.2	-	-	
U4 pin 2 to pin 3	170.0	330.5	336.3	-	-	
U4 pin 1 to pin 4	170.7	331.7	336.0	-	-	
U4 pin 2 to pin 4	168.5	328.0	335.5	-	-	
CY1 Pri. to CY2 Sec	168.4	328.8	335.9	-	-	
Between CY1	130.7	224.1	182.4	-	-	
Between CY2	60.08	87.15	173.8	-	-	
Model GTM96600-6554-P2 (+54Vdc/1.2A)	-	-	-	-	-	-
Output Vo+~Vo-	54.3	54.3Vdc	3.2	64.84	-	(Normal load):64.84W Output: 54.0V/1.2A
Output Vo+~Vo-	54.3	54.3Vdc	3.2	85.32	-	(Add load):85.32W Output: 53.99V/1.58A
T1 pin A - pin B (between C14)	54.3	54.3Vdc	3.2	87.62	-	(Add load):87.62 Output: 54.0V/1.62A
R21 short	5.24	5.44Vdc	0.32	-	-	(Normal load):64.84W

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8.4.2	TABLE: TABLE: Working Voltage / Power Measurement					P
						Output: 54.0V/1.2A
D7 short	0.145	0.72Vpk	0.96	-	-	(Normal load):64.84W Output: 54.0V/1.2A
C13 short	2.25	5.60Vdc	0.72	-	-	(Normal load):64.84W Output: 54.0V/1.2A
Model GTM96600-4005-TP3 (+5Vdc/8A)	-	-	-	-	-	-
Output Vo+~Vo-	5.20	5.20Vdc	0.32	39.07	-	(Normal load):39.07W Output: 4.88V/8A
Output Vo+~Vo-	5.20	5.20Vdc	0.32	43.84	-	(Add load):43.84 Output: 4.80V/9.1A
T1 pin A - pin B (between C14)	5.20	5.20Vdc	0.32	48,23	-	(Add load):48.23 Output: 4.80V/9.4A
D6 short	5.20	5.20Vdc	0.32	43.84	-	(Normal load):5V/8A Output: 4.82V/9A
R21 short	5.20	5.20Vdc	0.32	43.84	-	(Normal load):5V/8A Output: 4.82V/9A
Q2 pin S - pin D short	-	-	-	-	-	Unit shut down
U4 pin 1 - pin 2 short	-	-	-	-	-	Unit shut down
U4 pin 3 - pin 4 short	-	-	-	-	-	Unit shut down
U4 pin 1 open	-	-	-	-	-	Unit shut down
U4 pin 3 open	-	-	-	-	-	Unit shut down

Supplementary Information:

[1)]The input supply voltage to the ME EQUIPMENT was the RATED voltage or the voltage within the RATED voltage range which results in the highest measured value. See clause 8.5.4.

[2)]. If the d.c peak-to-peak ripple >10%, waveform considered as a.c. See clause 8.4.2

[3)] Voltage measurement of all conductive ACCESSIBLE PARTS of the SIP/SOP connection or separate power supply output connections to earth used a resistor of 10 kΩ + 500 Ω. See clause 8.4.2

8.4.3	TABLE: ME EQUIPMENT for connection to a power source by a plug - measurement of voltage or calculation of stored charge 1 s after disconnection of plug from mains supply	P
Maximum allowable voltage (V).....:	60	

Voltage measured (V)										
Voltage Measured Between:	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Plug pins 1 and 2	0	0	0	0	0	0	0	0	0	0
Plug pin 1 and plug earth pin	0	0	0	0	0	0	0	0	0	0

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Plug pin 2 and plug earth pin	0	0	0	0	0	0	0	0	0	0
Plug pin 1 and enclosure	0	0	0	0	0	0	0	0	0	0
Plug pin 2 and enclosure	0	0	0	0	0	0	0	0	0	0
Maximum allowable stored charge when measured voltage exceeded 60 v (μc).....:	**45**									
Calculated stored charge (μc)										
Voltage Measured Between:	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Plug pins 1 and 2										
Plug pin 1 and plug earth pin										
Plug pin 2 and plug earth pin										
Plug pin 1 and enclosure										
Plug pin 2 and enclosure										
Supplementary information: **Testing model: GTM96600-6554-TP3 (F3 insulation construction)**										

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Clause	Requirement + Test	Result - Remark	Verdict

8.4.4	TABLE: Internal capacitive circuits – measurement of residual voltage or calculation of the stored charge in capacitive circuits (i.e., accessible capacitors or circuit parts) after de-energizing ME EQUIPMENT		N/A
Maximum allowable residual voltage (V) ..... :			60 V
Maximum allowable stored charge when residual voltage exceeded 60 V ..... :			45 μC
Description of the capacitive circuit (i.e., accessible capacitor or circuit parts)	Measured residual voltage (V)	Calculated stored charge (μC)	Remarks
Supplementary information:			

8.5.5.1a	TABLE: defibrillation-proof applied parts – measurement of hazardous electrical energies				N/A
Test Condition: Figs. 9 & 10	Measurement made on accessible part	Applied part with test voltage	Test voltage polarity	Measured voltage between Y1 and Y2 (mV)	Remarks
Supplementary information:					

8.5.5.1b	TABLE: defibrillation-proof applied parts – verification of recovery time			N/A
Applied part with test voltage	Test voltage polarity	Recovery time from documents (s)	Measured recovery time (s)	Remarks
Supplementary information:				

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8.5.5.2	TABLE: DEFIBRILLATION-PROOF APPLIED PARTS or PATIENT CONNECTIONS of DEFIBRILLATION-PROOF APPLIED PARTS - Energy reduction test –measurement of Energy delivered to a 100 Ω load			N/A
Test Voltage applied to		Measured Energy E1 (mJ)	Measured Energy E2 (mJ)	Energy E1 as % of E2 (%)
PATIENT CONNECTION 1 or APPLIED PART with PATIENT CONNECTIONS 2, 3, and 4 of the same APPLIED PART connected to earth				
PATIENT CONNECTION 2 or APPLIED PART with PATIENT CONNECTIONS 1, 3, and 4 of the same APPLIED PART connected to earth				
PATIENT CONNECTION 3 or APPLIED PART with PATIENT CONNECTIONS 1, 2, and 4 of the same APPLIED PART connected to earth				
PATIENT CONNECTION 4 or APPLIED PART with PATIENT CONNECTIONS 1, 2, and 3 of the same APPLIED PART connected to earth				
Supplementary information: For compliance: E1 must at least 90% of E2 E1= Measured energy delivered to 100 Ω with ME Equipment connected; E2= Measured energy delivered to 100 Ω without ME equipment connected.				

8.6.4	TABLE: Impedance and current-carrying capability of PROTECTIVE EARTH CONNECTIONS				N/A
Type of ME EQUIPMENT & impedance measured between parts		Test current (A) /Duration (s)	Voltage drop measured between parts (V)	Maximum calculated impedance (mΩ)	Maximum allowable impedance (mΩ)
Supplementary information: PERMANENTLY INSTALLED ME EQUIPMENT, impedance between PROTECTIVE EARTH TERMINAL and a PROTECTIVELY EARTHED part - Limit 100 mΩME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the APPLIANCE INLET and a PROTECTIVELY EARTHED part - Limit 100 mΩ ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the protective earth pin on the DETACHABLE POWER SUPPLY CORD and a PROTECTIVELY EARTHED part - Limit 200 mΩ ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD, impedance between the protective earth pin in the MAINS PLUG and a PROTECTIVELY EARTHED part - Limit 200 mΩ					

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8.7	TABLE: leakage current	P

Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (μA)	Remarks
Fig. 13 - Earth Leakage (ER)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC
Model GTM96600-6554-TP3	-	-	After IP22	
ER, NC, S1 = 1, S5 = N	264	60	6.36	MD1 between PE terminal and earth (PE conductor open)
ER, NC, S1 = 1, S5 = R	264	60	7.05	Ditto
ER, SFC (Neutral Open), S1= 0, S5 = N	264	60	11.61	Ditto
ER, SFC (Neutral Open), S1= 0, S5 = R	264	60	11.63	Ditto
Non Fre weighted leakage	-	-	-	-
ER, NC Max.	264	60	202.4	
ER, SFC Max	264	60	198.7	
Model: GTM96600-6554-TP3EU	-	-	Before / After humidity	
ER, NC, S1 = 1, S5 = N	264	60	69.6/69.9	
ER, NC, S1 = 1, S5 = R	264	60	69.2/70.1	
ER, SFC (Neutral Open), S1= 0, S5 = N	264	60	117.7/117.9	
ER, SFC (Neutral Open), S1= 0, S5 = R	264	60	117.9/117.8	
Non Fre weighted leakage	-	-		
ER, NC Max.	264	60	244.2/245.4	
ER, SFC Max	264	60	264.4/267.8	
Fig. 14 - Touch Current (TC)	—	—	—	Maximum allowed values: 100 μA NC; 500 μA SFC
Model：GTM96600-6554-R2, GTM96600-6554-P2, GTM96600-6554-TP3	-	-	After IP22	
TC, NC, S1 = 1, S5 = N, S10 = 1	264	60	73.4/7.56/7.76	MD1 between output port and earth
TC, NC, S1 = 1, S5 = N, S10 = 0	264	60	72.4/66.8/68.7	Ditto
TC, NC, S1 = 1, S5 = R, S10 = 1	264	60	68.8/76.5/7.67	Ditto
TC, NC, S1 = 1, S5 = R, S10 = 0	264	60	77.5/78.6/78.8	Ditto
TC, SFC, S1 = 0, S5 = N, S10 = 1	264	60	175.6/177.2/177.1	Ditto
TC, SFC, S1 = 0, S5 = N, S10 = 0	264	60	175.5/176.9/173.9	Ditto
TC, SFC, S1 = 0, S5 = R, S10 = 1	264	60	177.3/177.2/176.9	Ditto
TC, SFC, S1 = 0, S5 = R, S10 = 0	264	60	177.2/178,7/177.1	Ditto

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Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (μA)	Remarks
TC, NC, S1 = 1, S5 = N, S10 = 1	264	60	5.68/5.45/5.65	MD2. between Plastic Enclosure (covered with metal foil) and earth
TC, NC, S1 = 1, S5 = N, S10 = 0	264	60	5.56/5.45/5.63	Ditto
TC, NC, S1 = 1, S5 = R, S10 = 1	264	60	5.46/5.66/5.53	Ditto
TC, NC, S1 = 1, S5 = R, S10 = 0	264	60	5.56/5.76/5.65	Ditto
TC, SFC, S1 = 0, S5 = N, S10 = 1	264	60	9.45/9.87/9.78	Ditto
TC, SFC, S1 = 0, S5 = N, S10 = 0	264	60	9.94/9.95/9.73	Ditto
TC, SFC, S1 = 0, S5 = R, S10 = 1	264	60	9.75/9.83/9.82	Ditto
TC, SFC, S1 = 0, S5 = R, S10 = 0	264	60	9.58/9.69/9.78	Ditto
TC, NC, S1 = 1, S5 = N, S10 = 1	264	60	6.45/6.35/6.63	MD3. between Plastic Enclosure (covered with metal foil) and output port
TC, NC, S1 = 1, S5 = N, S10 = 0	264	60	6.66/6.57/7.32	Ditto
TC, NC, S1 = 1, S5 = R, S10 = 1	264	60	6.64/6.58/6.67	Ditto
TC, NC, S1 = 1, S5 = R, S10 = 0	264	60	6.38/6.53/6.32	Ditto
TC, SFC, S1 = 0, S5 = N, S10 = 1	264	60	12.75/12.55/12.54	Ditto
TC, SFC, S1 = 0, S5 = N, S10 = 0	264	60	12.78/12.96/12.56	Ditto
TC, SFC, S1 = 0, S5 = R, S10 = 1	264	60	13.01/12.99/12.97	Ditto
TC, SFC, S1 = 0, S5 = R, S10 = 0	264	60	13.12/13.02/12.99	Ditto
Non Fre weighted leakage	-	-	-	-
TC, NC Max.	264	60	190.9/200.1/201.2	-
TC, SFC Max	264	60	180.3/181.1/180.9	-
Model: GTM96600-6554-TP3EU	-	-	Before / After humidity	
TC, NC, S1 = 1, S5 = N, S10 = 1	264	60	60.2/70.8	MD1 between output port and earth
TC, NC, S1 = 1, S5 = N, S10 = 0	264	60	60.1/71.4	Ditto

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Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks
TC, NC, S1 = 1, S5 = R, S10 = 1	264	60	61.0/70.8	Ditto
TC, NC, S1 = 1, S5 = R, S10 = 0	264	60	61.2/71	Ditto
TC, SFC, S1 = 0, S5 = N, S10 = 1	264	60	98.9/114.5	Ditto
TC, SFC, S1 = 0, S5 = N, S10 = 0	264	60	98.8/114.7	Ditto
TC, SFC, S1 = 0, S5 = R, S10 = 1	264	60	99.2/114.3	Ditto
TC, SFC, S1 = 0, S5 = R, S10 = 0	264	60	99.5/114.4	Ditto
TC, NC, S1 = 1, S5 = N, S10 = 1	264	60	4.54/5.21	MD2. between Plastic Enclosure (covered with metal foil) and earth
TC, NC, S1 = 1, S5 = N, S10 = 0	264	60	4.53/5.22	Ditto
TC, NC, S1 = 1, S5 = R, S10 = 1	264	60	4.53/5.24	Ditto
TC, NC, S1 = 1, S5 = R, S10 = 0	264	60	4.55/5.45	Ditto
TC, SFC, S1 = 0, S5 = N, S10 = 1	264	60	5.6/8.9	Ditto
TC, SFC, S1 = 0, S5 = N, S10 = 0	264	60	5.65/8.97	Ditto
TC, SFC, S1 = 0, S5 = R, S10 = 1	264	60	7.68/8.92	Ditto
TC, SFC, S1 = 0, S5 = R, S10 = 0	264	60	7.85/8.93	Ditto
TC, NC, S1 = 1, S5 = N, S10 = 1	264	60	1.33/1.41	MD3. between Plastic Enclosure (covered with metal foil) and output port
TC, NC, S1 = 1, S5 = N, S10 = 0	264	60	1.45/1.55	Ditto
TC, NC, S1 = 1, S5 = R, S10 = 1	264	60	1.11/1.12	Ditto
TC, NC, S1 = 1, S5 = R, S10 = 0	264	60	1.12/1.03	Ditto
TC, SFC, S1 = 0, S5 = N, S10 = 1	264	60	5.35/5.71	Ditto
TC, SFC, S1 = 0, S5 = N, S10 = 0	264	60	5.23/5.46	Ditto
TC, SFC, S1 = 0, S5 = R, S10 = 1	264	60	5.53/5.73	Ditto
TC, SFC, S1 = 0, S5 = R, S10 = 0	264	60	5.38/5.46	Ditto
Non Fre weighted leakage	-	-		-
TC, NC Max.	264	60	545/556	-
TC, SFC Max	264	60	496/501	-
Fig. 15 - Patient Leakage Current (P)	—	—	—	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current); 100 µA NC; 500 µA SFC (a.c.) Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current)
Fig. 16 - Patient leakage current with mains on the F-type applied parts (PM)	—	—	—	Maximum allowed values: Type B: N/A Type BF AP: 5000 µA

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Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (μA)	Remarks
				Type CF AP: 50 μA
Fig. 17 - Patient leakage current with external voltage on Signal Input/Output part (SIP/SOP)	—	—	—	Maximum allowed values: Type B or BF AP: 10 μA NC; 50 μA SFC(d.c. current); 100 μA NC; 500 μA SFC (a.c.) ; Type CF AP: 10 μA NC; 50 μA SFC (d.c. or a.c. current)
Fig. 18 - Patient leakage current with external voltage on metal Accessible Part that is not Protectively Earthed	—	—	—	Maximum allowed values: Type B or BF AP: 500 μA Type CF: N/A
Fig. 19 – Patient Auxiliary Current	—	—	—	Maximum allowed values: Type B or BF AP: 10 μA NC; 50 μA SFC (d.c. current); 100 μA NC; 500 μA SFC (a.c.) ; Type CF AP: 10 μA NC;50 μA SFC (d.c. or a.c. current)
Fig. 15 and 20 – Total Patient Leakage Current with all AP of same type connected together	—	—	—	Maximum allowed values: Type B or BF AP: 50 μA NC; 100μA SFC (d.c. current); 500 μA NC; 1000 μA SFC (a.c.); Type CF AP: 50 μA NC; 100 μA SFC (d.c. or a.c. current)
Fig. 17 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on SIP/SOP	—	—	—	Maximum allowed values: Type B or BF AP: 50 μA NC; 100μA SFC (d.c. current); 500 μA NC;1000 μA SFC (a.c.); Type CF AP: 50 μA NC; 100 μA

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Clause	Requirement + Test	Result - Remark	Verdict

Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (μA)	Remarks
				SFC (d.c. or a.c. current)
Fig. 16 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on F-type AP	—	—	—	Maximum allowed values: Type B: NA Type BF: 5000 μA Type CF: 100 μA
Fig. 18 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on metal Accessible Part not Protectively Earthed	—	—	—	Maximum allowed values: Type B & BF: 1000 μA Type CF: N/A
Function Earth Conductor Leakage Current (FECLC)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC

Supplementary information:

After IP22 testing sequence: Model： GTM96600-6554-R2 (F1 insulation construction), GTM96600-6554-P2 (F1 insulation construction), GTM96600-6554-TP3 (F2 insulation construction).

F1, F2, and E2 insulation construction models use max. 2200pF CY1 and CY2 in series. Leakage current tests on F2 insulation construction model can cover E2 insulation construction model.

Before/After humidity test model: GTM96600-6554-TP3EU (F3 insulation construction). F3 insulation construction models use max. 1500pF CY1 and CY2 in series.

Above test conditions were choose as worst-case conditions.

Note 1: For EARTH LEAKAGE CURRENT see 8.7.3 d) and 8.7.4.5;
Note 2: For TOUCH CURRENT see 8.7.3 c) and 8.7.4.6;

Note 3: For PATIENT LEAKAGE CURRENT SEE 8.7.3.b) and 8.7.4.7
Note 4: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS of the same type. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

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Clause	Requirement + Test	Result - Remark	Verdict

Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (μA)	Remarks
Note 5: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of Clause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate matter, cleaning & disinfection, & sterilization).				
ER - Earth leakage current TC – Touch current P - Patient leakage current PA – Patient auxiliary current TP – Total Patient current PM - Patient leakage current with mains on the applied parts MD - Measuring device				A - After humidity conditioning B - Before humidity conditioning 1 - Switch closed or set to normal polarity 0 - Switch open or set to reversed polarity NC - Normal condition SFC - Single fault condition

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Clause	Requirement + Test	Result - Remark	Verdict

8.8.3	TABLE: Dielectric strength test of solid insulating materials with safety function – MEANS OF OPERATOR PROTECTION (MOOP) / MEANS OF PATIENT PROTECTION (MOPP)				P
Insulation under test (area from insulation diagram)	**Insulation Type (1 or 2 MOOP/MOPP)**	**Reference Voltage**		**A.C. test voltages in V r.m.s[1)]**	**Dielectric breakdown after 1 minute Yes/No[2)]**
		PEAK WORKING VOLTAGE (U) V_{peak}	**PEAK WORKING VOLTAGE (U) V d.c.**		
Model: GTM96600-6554-TP3	-	-	-	-	Before humidity
A: Between L and N	1 MOOP	340	-	1500	No
D: Between L/N and Plastic enclosure	2 MOPP	340	-	4000	No
C: Primary circuit and secondary circuit	2 MOPP	387	-	4095	No
Model：GTM96600-6554-R3A	-	-	-	-	After IP22
A: Between L and N	1 MOOP	340	-	1500	No
D: Between L/N and Plastic enclosure	2 MOPP	340	-	4000	No
C: Primary circuit and secondary circuit	2 MOPP	387	-	4095	No
Model: GTM96600-6554-P2	-	-	-	-	After IP22
A: Between L and N	1 MOOP	340	-	1500	No
D: Between L/N and Plastic enclosure	2 MOPP	340	-	4000	No
C: Primary circuit and secondary circuit	2 MOPP	387	-	4095	No
Model: GTM96600-6554-TPNA	-	-	-	-	After IP22
A: Between L and N	1 MOOP	340	-	1500	No
D: Between L/N and Plastic enclosure	2 MOPP	340	-	4000	No
C: Primary circuit and secondary circuit	2 MOPP	387	-	4095	No
-	-	-	-	-	After humidity
Transformer (T1): TF061	2 MOPP	387	-	4095	No
TIW, Type TRW(B)	2 MOPP X 2	387	-	8190	No
Insulation tape (All types)	1 MOPP	340	-	1500	No
Insulator (All types)	2 MOPP	340	-	4000	No
Model: GTM96600-6554-TP3EU	-	-	-	-	After humidity
A: Between L and N	1 MOOP	340	-	1500	No

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D: Between L/N and Plastic enclosure	2 MOPP	340	-	4000	No
C: Primary circuit and secondary circuit	2 MOPP	387	-	4095	No
TIW, Type THL-F-xx	2 MOPP X 2	387	-	8190	No
Supplementary information: [1] Alternatively, per the Table (i.e., __dc), a d.c. test voltage equal to the peak value of the a.c. test voltage used. [2] A) Immediately after humidity treatment of 5.7, ME EQUIPMENT de-energized, B) after required sterilization PROCEDURE, ME EQUIPMENT de-energized, C) after reaching steady state operating temperature as during heating test of 11.1.1, and D) after relevant tests of 11.6 (i.e., overflow, spillage, leakage, ingress of water, cleaning, disinfection, and sterilization).					

8.8.4.1	TABLE: Resistance to heat - Ball pressure test of thermoplastic parts		P
	Allowed impression diameter (mm) .....:	≤ 2 mm	—
	Force (N).....:	20	—

Part/material	Test temperature (°C)	Impression diameter (mm)
Enclosure/External insulating parts	-	-
Plastic enclosure (Model GTM96600-6554-P2, Enclosure CX7211(GG))	122	1.1
Plastic enclosure (Model GTM96600-6554-R3A, (Enclosure 945(GG))	122	1.3
Insulating material supporting un-insulated Mains Parts	-	-
Supplementary information: resistance to heat for insulation of thermoplastic materials that used as SUPPLEMENTARY INSULATION or REINFORCED INSULATION established by performing the ball-pressure test in at a temperature 25 °C higher than the temperature of the insulation measured during the tests of 13.2.2 to 13.2.13 (inclusive).		

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Clause	Requirement + Test	Result - Remark	Verdict

8.9.2	TABLE: Short circuiting of each single one of the CREEPAGE DISTANCES and AIR CLEARANCES for insulation in the MAINS PART between parts of opposite polarity in lieu of complying with the required measurements in 8.9.4		N/A
Specific areas of circuits short-circuited and test conditions	**Test in lieu of CREEPAGE DISTANCE or AIR CLEARANCE[1)]**	**HAZARDOUS SITUATION observed (i.e., fire hazard, shock hazard, explosion, discharge of parts, etc.)? Yes/No**	**Remarks**
Supplementary information: [1)] Note: AC - AIR CLEARANCE CD - CREEPAGE DISTANCE			

8.9.3.2	Table: Thermal cycling tests on one sample of insulating compound forming solid insulation between conductive parts			N/A
Part Test	**8.9.3.4 - Test duration and temperature for 10 cycles after which the sample was subjected to Humidity Preconditioning per Cl. 5.7**	**Dielectric test voltage**	**Dielectric strength test after humidity preconditioning per cl. 5.7 except for 48 h only, Breakdown: Yes/No**	**Crack or voids in the insulating compound: Yes/No**
	68 h at T1 ± 2 °C = ___°C [1)]			
	1 h at 25 °C ± 2 °C			
	2 h at 0 °C ± 2 °C			
	1 or more h at 25 °C ± 2 °C			
Supplementary information: [1)] T1 = 10 °C above the maximum temperature of relevant part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another.				

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Clause	Requirement + Test	Result - Remark	Verdict

8.9.3.3	Table: Thermal cycling tests on one sample of cemented joint with other insulating parts (see 8.9.3.3)			N/A
Part tested	**Sample**	**Each test duration and temperature**	**Dielectric test voltage**	**Dielectric strength test Breakdown: Yes/No**
	1	10 Cycles conducted of the following:		
		1 - 68 h at T1 ± 2 °C = ___°C[1]		
		2 - 1 h at 25 °C ± 2 °C		
		3 - 2 h at 0 °C ± 2 °C		
		4 - 1 or more h at 25 °C ± 2 °C		
	2	Humidity Conditioning per 5.7		
	3	Humidity Conditioning per 5.7		

Supplementary information:

[1)] T1 = 10 °C above the maximum temperature of relevant part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another.

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8.10	TABLE: Critical components information	-

8.10 b	TABLE: List of identified components with HIGH INTEGRITY CHARACTERISTICS	-

8.11.3.5	TABLE: CORD ANCHORAGES			P
Cord under test	**Mass of equipment (kg)**	**Pull (N)**	**Torque Nm)**	**Remarks**
Model GTM96600-6554-P2	0.579	30	0.1	Movement: 0.2mm
Supplementary information:				

8.11.3.6	TABLE: Cord guard		P
Cord under test	**Test mass**	**Measured curvature**	**Remarks**
Test method per 3rd ed	-	-	-
Model GTM96600-6554-P2	0.238	8.5	-
Supplementary information:			

9.2.2.2	TABLE: Measurement of gap "a" according to Table 20 (ISO 13852: 1996)			N/A
Part of body	**Allowable adult gap[1], mm**	**Measured adult gap, mm**	**Allowable children gap[1], mm**	**Measured children gap, mm**
Body	**> 500**		**> 500**	
Head	**> 300 or < 120**		**> 300 or < 60**	
Leg	**> 180**		**> 180**	
Foot	**> 120 or < 35**		**> 120 or < 25**	
Toes	**> 50**		**> 50**	
Arm	**> 120**		**> 120**	
Hand, wrist, fist	**> 100**		**> 100**	
Finger	**> 25 or < 8**		**> 25 or < 4**	
Supplementary information: [1] In general, gaps for adults used, except when the device is specifically designed for use with children, values for children applied.				

9.2.3.2	TABLE: Over-travel End Stop Test	N/A
ME EQUIPMENT end stop	Test Condition (cycles, load, speed)	Remarks
Supplementary information:		

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9.4.2.1	TABLE: Instability—overbalance in transport position	N/A
ME EQUIPMENT preparation	**Test Condition (transport position)**	**Remarks**
Supplementary information:		

9.4.2.2	TABLE: Instability—overbalance excluding transport position	N/A
ME EQUIPMENT preparation	**Test Condition (excluding transport position) Test either 5 ° incline and verify Warning marking or 10 ° incline)**	**Remarks**
Supplementary information:		

9.4.2.3	TABLE: Instability—overbalance from horizontal and vertical forces	N/A
ME EQUIPMENT preparation	**Test Condition (force used, direction of force, weight of equipment, location of force)**	**Remarks**
Supplementary information:		

9.4.2.4.2	TABLE: Castors and wheels – Force for propulsion	N/A
ME EQUIPMENT preparation	**Test Condition (force location and height)**	**Remarks**
Supplementary information:		

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9.4.2.4.3	TABLE: Castors and wheels – Movement over a threshold	N/A
ME EQUIPMENT preparation	**Test Condition (speed of movement)**	**Remarks**
Supplementary information:		

9.4.3.1	TABLE: Instability from unwanted lateral movement (including sliding) in transport position	N/A
ME EQUIPMENT Preparation	**Test Condition (transport position, working load, locking device(s), caster position)**	**Remarks**
Supplementary information:		

9.4.3.2	TABLE: Instability from unwanted lateral movement (including sliding) excluding transport position	N/A
ME EQUIPMENT Preparation	**Test Condition (working load, locking device(s), caster position, force, force location, force direction)**	**Remarks**
Supplementary information:		

9.4.4	TABLE: Grips and other handling devices	N/A
Clause and Name of Test	**Test Condition**	**Remarks**
Supplementary information:		

9.7.5	TABLE: Pressure vessels	N/A

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9.7.5	TABLE: Pressure vessels				N/A
Hydraulic, Pneumatic or Suitable Media and Test Pressure	**Vessel Burst**	**Permanent Deformation**	**Leaks**	**Vessel fluid substance**	**Remarks**
Supplementary Information:					

9.8.3.2	TABLE: PATIENT support/suspension system - Static forces			N/A
ME EQUIPMENT part or area	Position	**Load**	**Area**	**Remarks**
Supplementary Information:				

9.8.3.3	TABLE: Support/Suspension System – Dynamic forces due to loading from persons			N/A
ME EQUIPMENT part or area	**Position**	**Safe Working Load**	**Area**	**Remarks**
Supplementary Information:				

10.1.1	TABLE: Measurement of X - radiation		N/A
Maximum allowable radiation pA/kg (µSv/h) (mR/h)	**36 (5 µSv/h) (0.5 mR/h)**		
Surface area under test Surface no./ Description[1)]	**Measured Radiation, pA/kg (µSv/h) (mR/h)**	Remarks	

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1/ /		
2/ /		
3/ /		
4/ /		
5/ /		
6/ /		
7/ /		
8/ /		
9/ /		
10/ /		
Supplementary information: 1) Measurements made at 5 cm from any surface to which OPERATOR (other than SERVICE PERSONNEL) can gain access without a TOOL, is deliberately provided with means of access, or is instructed to enter regardless of whether or not a TOOL is needed to gain access		

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11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT					P
Model No. .....:		See below				
Test ambient (°C) .....:		Adjusted to 40				
Test supply voltage/frequency (V/Hz)[4] ..:		See below				

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP[5] (°C)	Max measured temperature[2], (°C)	Remarks
Model GTM96600-4005-TP3 (label down), 85V AC, 60Hz (Load condition: +5Vdc/8A)					
	CH001	Plug holder	86	41.4	Touch time: t < 1s
	CH002	Power supply cord	60	47.8	
	CH003	Primary internal wire	80	66.9	
	CH004	MOV1	105	79.8	
	CH005	CX1	105	86.4	
	CH006	LF2	130	93.2	
	CH007	PCB under BD1	130	83.8	
	CH008	C1	REF	91.3	
	CH009	CY1	125	87.8	
	CH010	CY2	125	79.4	
	CH101	T1 primary winding	120	104.4	Class B
	CH102	T1 secondary winding	120	99.9	Class B
	CH103	Output wire	80	70.6	
	CH104	Enclosure inside near T1	90	77.2	
	CH105	Enclosure outside near T1	86	66.5	Touch time: t < 1s
	CH106	Enclosure inside near HS1	90	78.7	
	CH107	Enclosure outside near HS1	86	68.6	Touch time: t < 1s
	CH108	Label	80	78.3	Touch time: t < 1s This also refer as the test result for test corner
	CH108	Test corner	90	78.3	
	CH201	Ambient	-	40	
Model GTM96600-4005-TP3 (label down), 264V AC, 50Hz (Load condition: +5Vdc/8A)					

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Clause	Requirement + Test	Result - Remark	Verdict

	CH001	Plug holder	86	41.2	Touch time: t < 1s
	CH002	Power supply cord	60	46.1	
	CH003	Primary internal wire	80	60.1	
	CH004	MOV1	105	70.6	
	CH005	CX1	105	73.8	
	CH006	LF2	130	75.4	
	CH007	PCB under BD1	130	68.8	
	CH008	C1	REF	77.7	
	CH009	CY1	125	80.4	
	CH010	CY2	125	73.9	
	CH101	T1 primary winding	120	96.2	Class B
	CH102	T1 secondary winding	120	90.9	Class B
	CH103	Output wire	80	67.4	
	CH104	Enclosure inside near T1	90	69.8	
	CH105	Enclosure outside near T1	86	61.4	Touch time: t < 1s
	CH106	Enclosure inside near HS1	90	71.5	
	CH107	Enclosure outside near HS1	86	65.3	Touch time: t < 1s
	CH108	Label	80	70.1	Touch time: t < 1s This also refer as the test result for test corner
	CH108	Test corner	90	70.1	
	CH201	Ambient	-	40	
Model GTM96600-6554-TP3 (label down), 264V AC, 50Hz (Load condition: +54Vdc/1.2A)					
	CH001	Plug holder	86	41.0	Touch time: t < 1s
	CH002	Power supply cord	60	47.0	
	CH003	Primary internal wire	80	62.5	
	CH004	MOV1	105	73.6	
	CH005	CX1	105	75.4	
	CH006	LF2	130	79.4	
	CH007	PCB under BD1	130	73.2	
	CH008	C1	REF	83.2	
	CH009	CY1	125	81.7	
	CH010	CY2	125	88.6	
	CH101	T1 primary winding	120	94.4	Class B

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Clause	Requirement + Test	Result - Remark	Verdict

	CH102	T1 secondary winding	120	97.3	Class B
	CH103	Output wire	80	58.4	
	CH104	Enclosure inside near T1	90	74.8	
	CH105	Enclosure outside near T1	86	66.7	Touch time: t < 1s
	CH106	Enclosure inside near HS1	90	77.2	
	CH107	Enclosure outside near HS1	86	65.4	Touch time: t < 1s
	CH108	Label	80	77.3	Touch time: t < 1s This also refer as the test result for test corner
	CH108	Test corner	90	77.3	
	CH201	Ambient	-	40	
Model GTM96600-6554-TP3 (with insulator and copper foil) (label down), 264V AC, 50Hz (Load condition: +54Vdc/1.2A)					
	CH001	Plug holder	86	43.1	Touch time: t < 1s
	CH002	Power supply cord	60	51.5	
	CH003	Primary internal wire	80	73.0	
	CH004	MOV1	105	85.1	
	CH005	CX1	105	90.5	
	CH006	LF2	130	103.6	
	CH007	PCB under BD1	130	92.2	
	CH008	C1	REF	95.2	
	CH009	CY1	125	90.3	
	CH010	CY2	125	91.8	
	CH101	T1 primary winding	120	98.7	Class B
	CH102	T1 secondary winding	120	102.6	Class B
	CH103	Output wire	80	65.9	
	CH104	Enclosure inside near T1	90	83.4	
	CH105	Enclosure outside near T1	86	74.4	Touch time: t < 1s
	CH106	Enclosure inside near HS1	90	79.0	
	CH107	Enclosure outside near HS1	86	69.3	Touch time: t < 1s
	CH108	Label	80	76.2	Touch time: t < 1s This also refer as the test result for test corner

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Clause	Requirement + Test	Result - Remark	Verdict

	CH108	Test corner	90	76.2	
	CH201	Ambient	-	40.0	
Model GTM96600-6554-P2(label up), 85V AC, 60Hz (Load condition: +54Vdc/1.2A)					
	CH001	Plug holder	86	41.1	Touch time: t < 1s
	CH002	Power supply cord	60	52.7	
	CH003	Primary internal wire	80	69.0	
	CH004	MOV1	105	74.3	
	CH005	CX1	105	77.7	
	CH006	LF2	130	81.1	
	CH007	PCB under BD1	130	80.1	
	CH008	C1	REF	81.1	
	CH009	CY1	125	80.3	
	CH010	CY2	125	80.6	
	CH101	T1 primary winding	120	83.4	Class B
	CH102	T1 secondary winding	120	81.7	Class B
	CH103	Output wire	80	62.9	
	CH104	Enclosure inside near T1	90	75.8	
	CH105	Enclosure outside near T1	86	70.5	Touch time: t < 1s
	CH106	Enclosure inside near HS1	90	74.1	
	CH107	Enclosure outside near HS1	86	64.9	Touch time: t < 1s
	CH108	Label	80	79.1	Touch time: t < 1s This also refer as the test result for test corner
	CH108	Test corner	90	79.1	
	CH201	Ambient	-	40	
Model GTM96600-4005-P2(label up), 85V AC, 60Hz (Load condition: +5Vdc/8A)					
	CH001	Inlet	Ref	72.4	
	CH002	MOV1	105	83.2	
	CH003	CX1	105	89.5	
	CH004	LF2	130	103.4	
	CH005	PCB under BD1	130	87.9	
	CH006	C1	REF	97.1	
	CH007	CY1	125	89.5	
	CH008	CY2	125	76.6	

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	CH009	T1 primary winding	120	98.5	Class B
	CH010	T1 secondary winding	120	98.2	Class B
	CH101	Output wire	80	60.4	
	CH102	Enclosure inside near T1	90	79.8	
	CH103	Enclosure outside near T1	86	72.0	Touch time: t < 1s
	CH104	Enclosure inside near HS1	90	71.6	
	CH105	Enclosure outside near HS1	86	62.5	Touch time: t < 1s
	CH106	Label	80	78.7	Touch time: t < 1s This also refer as the test result for test corner
	CH106	Test corner	90	78.7	
	CH109	Ambient	-	40	
SFC temperature test					
Model GTM96600-4005-TP3 (T1 pin A - B overload (between C14) (label down), 264V AC, 50Hz (Load condition: +54Vdc/1.2A)					
	CH001	Plug holder	86	41.4	Touch time: t < 1s
	CH002	Power supply cord	77.5	47.4	
	CH003	Primary internal wire	107.5	64.2	
	CH004	MOV1	145	75.0	
	CH005	CX1	145	79.1	
	CH006	LF2	182.5	80.9	
	CH007	PCB under BD1	182.5	73.6	
	CH008	C1	Ref	83.5	
	CH009	CY1	175	86.2	
	CH010	CY2	175	79.4	
	CH101	T1 primary winding	165	104.4	Class B
	CH102	T1 secondary winding	165	98.3	Class B
	CH103	Output wire	107.5	69.6	
	CH104	Enclosure inside near T1	122.5	75.6	
	CH105	Enclosure outside near T1	86	62.5	Touch time: t < 1s
	CH106	Enclosure inside near HS1	122.5	75.6	
	CH107	Enclosure outside near HS1	86	68.0	Touch time: t < 1s

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Clause	Requirement + Test	Result - Remark	Verdict

	CH108	Label	86	75.2	Touch time: t < 1s This also refer as the test result for test corner
	CH108	Test corner	90	75.2	
	CH201	Ambient	-	40	
Model GTM96600-4005-TP3 (T1 pin A - B overload (between C14) (with insulator and copper foil) (label down), 264V AC, 50Hz (Load condition: +54Vdc/1.2A)					
	CH001	Plug holder	86	40.3	Touch time: t < 1s
	CH002	Power supply cord	77.5	42.3	
	CH003	Primary internal wire	107.5	78.6	
	CH004	MOV1	145	95.4	
	CH005	CX1	145	104.3	
	CH006	LF2	182.5	113.5	
	CH007	PCB under BD1	182.5	99.4	
	CH008	C1	Ref	110.2	
	CH009	CY1	175	107.1	
	CH010	CY2	175	91.7	
	CH101	T1 primary winding	165	129.0	Class B
	CH102	T1 secondary winding	165	122.4	Class B
	CH103	Output wire	107.5	77.9	
	CH104	Enclosure inside near T1	122.5	94.2	
	CH105	Enclosure outside near T1	86	73.3	Touch time: t < 1s
	CH106	Enclosure inside near HS1	122.5	94.0	
	CH107	Enclosure outside near HS1	86	75.0	Touch time: t < 1s
	CH108	Label	86	80.2	Touch time: t < 1s This also refer as the test result for test corner
	CH108	Test corner	90	80.2	
	CH201	Ambient	-	40	
Model GTM96600-6554-TP3 (T1 pin A - B overload (between C14) (with insulator and copper foil) (label down), 80V AC, 60Hz (Load condition: +54Vdc/1.2A)					
	CH001	Plug holder	86	46.5	Touch time: t < 1s

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Clause	Requirement + Test	Result - Remark	Verdict

	CH002	Power supply cord	77.5	54.2	
	CH003	Primary internal wire	107.5	83.6	
	CH004	MOV1	145	96.6	
	CH005	CX1	145	103.9	
	CH006	LF2	182.5	117.5	
	CH007	PCB under BD1	182.5	105.9	
	CH008	C1	Ref	110.0	
	CH009	CY1	175	104.7	
	CH010	CY2	175	105.5	
	CH101	T1 primary winding	165	113.7	Class B
	CH102	T1 secondary winding	165	122.0	Class B
	CH103	Output wire	107.5	71.4	
	CH104	Enclosure inside near T1	122.5	96.7	
	CH105	Enclosure outside near T1	86	85.1	Touch time: t < 1s
	CH106	Enclosure inside near HS1	122.5	89.0	
	CH107	Enclosure outside near HS1	86	76.2	Touch time: t < 1s
	CH108	Label	86	84.7	Touch time: t < 1s This also refer as the test result for test corner
	CH108	Test corner	90	84.7	
	CH201	Ambient	-	40	
Model GTM96600-6554-TP3 (T1 pin A - B overload (between C14) (with insulator and copper foil) (label down), 264V AC, 50Hz (Load condition: +54Vdc/1.2A)					
	CH001	Plug holder	86	41.2	Touch time: t < 1s
	CH002	Power supply cord	77.5	49.7	
	CH003	Primary internal wire	107.5	67.7	
	CH004	MOV1	145	80.3	
	CH005	CX1	145	82.6	
	CH006	LF2	182.5	86.0	
	CH007	PCB under BD1	182.5	79.6	
	CH008	C1	Ref	85.0	
	CH009	CY1	175	86.5	
	CH010	CY2	175	91.0	

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Clause	Requirement + Test	Result - Remark	Verdict

	CH101	T1 primary winding	165	98.3	Class B
	CH102	T1 secondary winding	165	112.8	Class B
	CH103	Output wire	107.5	64.4	
	CH104	Enclosure inside near T1	122.5	80.0	
	CH105	Enclosure outside near T1	86	72.0	Touch time: t < 1s
	CH106	Enclosure inside near HS1	122.5	80.4	
	CH107	Enclosure outside near HS1	86	69.8	Touch time: t < 1s
	CH108	Label	86	72.6	Touch time: t < 1s This also refer as the test result for test corner
	CH108	Test corner	90	72.6	
	CH201	Ambient	-	40	
Model GTM96600-6554-TP3 （with insulator and copper foil） (label down), 80V AC, 60Hz Output overload					
	CH001	Plug holder	86	44.1	Touch time: t < 1s
	CH002	Power supply cord	77.5	54.8	
	CH003	Primary internal wire	107.5	82.7	
	CH004	MOV1	145	97.1	
	CH005	CX1	145	104.4	
	CH006	LF2	182.5	120.8	
	CH007	PCB under BD1	182.5	106.4	
	CH008	C1	Ref	109.2	
	CH009	CY1	175	104.6	
	CH010	CY2	175	106.2	
	CH101	T1 primary winding	165	114.8	Class B
	CH102	T1 secondary winding	165	122.3	Class B
	CH103	Output wire	107.5	74.0	
	CH104	Enclosure inside near T1	122.5	95.8	
	CH105	Enclosure outside near T1	86	84.7	Touch time: t < 1s
	CH106	Enclosure inside near HS1	122.5	89.0	
	CH107	Enclosure outside near HS1	86	76.3	Touch time: t < 1s

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Clause	Requirement + Test	Result - Remark	Verdict

	CH108	Label	86	85.8	Touch time: t < 1s This also refer as the test result for test corner
	CH108	Test corner	90	85.8	
	CH201	Ambient	-	40	
Model GTM96600-6554-P2 (label up), 80V AC, 60Hz Output Overload					
	CH001	Plug holder	86	41.4	Touch time: t < 1s
	CH002	Power supply cord	77.5	56.0	
	CH003	Primary internal wire	107.5	73.1	
	CH004	MOV1	145	79.2	
	CH005	CX1	145	82.5	
	CH006	LF2	182.5	86.2	
	CH007	PCB under BD1	182.5	85.5	
	CH008	C1	Ref	86.2	
	CH009	CY1	175	85.0	
	CH010	CY2	175	85.2	
	CH101	T1 primary winding	165	88.3	Class B
	CH102	T1 secondary winding	165	86.0	Class B
	CH103	Output wire	107.5	65.0	
	CH104	Enclosure inside near T1	122.5	76.8	
	CH105	Enclosure outside near T1	86	67.6	Touch time: t < 1s
	CH106	Enclosure inside near HS1	122.5	77.9	
	CH107	Enclosure outside near HS1	86	68.2	Touch time: t < 1s
	CH108	Label	86	-	Touch time: t < 1s This also refer as the test result for test corner
	CH108	Test corner	90	-	
	CH201	Ambient	-	40	
Model GTM96600-6554-P2 (label up), 80V AC, 60Hz Output Overload					
	CH108	Label	86	82.3	Touch time: t < 1s This also refer as the test result for test corner

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Clause	Requirement + Test	Result - Remark	Verdict

	CH108	Test corner	90	82.3	
	CH201	Ambient	-	40	

Supplementary information:

[1] Maximum allowable temperature on surfaces of test corner is 90 °C

[2] Max temperature determined in accordance with 11.1.3e)

[3] When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.

[4] Supply voltage:

- ME EQUIPMENT with heating elements - 110 % of the maximum RATED voltage;
- Motor operated ME EQUIPMENT - least favourable voltage between 90 % of the minimum RATED and 110 % of the maximum RATED voltage. ME EQUIPMENT operated under normal load and normal DUTY CYCLE.

- Combined heating and motor operated and other ME EQUIPMENT - tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage.

[5] **APPLIED PARTS** intended to supply heat to a **PATIENT - S**ee RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.

Information from Risk Management, as applicable**:**

11.1.3d	TABLE: Temperature of windings by change-of-resistance method						N/A
Temperature T of winding:	**t_1 (°C)**	**R_1 (Ω)**	**t_2 (°C)**	**R_2 (Ω)**	**T (°C)**	**Allowed T_{max} (°C)**	**Insulation class**

Supplementary information:

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

11.2.2.1	TABLE: Alternative method to 11.2.2.1 a) 5) to determine existence of an ignition source		N/A
Areas where sparking might cause ignition:		**Remarks**	
1.			
2.			
3.			
4.			
5.			
6.			
Materials of the parts between which sparks could occur (Composition, Grade Designation, Manufacturer):		**Remarks**	
1.			
2.			
3.			
4.			
5.			
6.			
Test parameters selected representing worst case conditions for ME EQUIPMENT:		**Remarks**	
Oxygen concentration (%)..... :			
Fuel ..... :			
Current (A) ..... :			
Voltage (V)..... :			
Capacitance (μF) ..... :			
Inductance or resistance (h or Ω).... :			
No. of trials (300 Min) ..... :			
Sparks resulted in ignition (Yes/No) :			
Supplementary information: Test procedure of 11.2.2.1 a) 5) & Figs 35-37 used for tests. For circuits not in Figs 35-37, test voltage or current set at 3 times the worst-case values with other parameters set at worst case values to determine if ignition can occur. Information from Risk Management, as applicable:			

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

11.6.1	TABLE: overflow, spillage, leakage, ingress of water, cleaning, disinfection, sterilization, compatibility with substances		P
Clause / Test Name	**Test Condition**	**Part under test**	**Remarks**
Cl.11.6.5, Ingress	IP2X	Model GTM96600-6554-TP (F2 construction)	Label up, cannot access to live part
Cl.11.6.5, Ingress	IPX2	Model GTM96600-6554-TP (F2 construction)	Label up, no water got inside the enclosure
Cl.11.6.5, Ingress	IP2X	Model GTM96600-6554-R3A (E2 construction)	Remove access cover, label up, cannot access to live part
Cl.11.6.5, Ingress	IPX2	Model GTM96600-6554-R3A (E2 construction)	Remove access cover, label up, no water got inside the enclosure
Cl.11.6.5, Ingress	IP2X	Model GTM96600-6554-P2 (F1 construction)	Label up, cannot access to live part
Cl.11.6.5, Ingress	IPX2	Model GTM96600-6554-P2 (F1 construction)	Label up, no water got inside the enclosure
Supplementary information: Information from Risk Management, as applicable:			

13.1.2	TABLE: measurement of power or energy dissipation in parts & components to waive SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances			N/A
Power dissipated less than (W) ..... :		**15**		
Energy dissipated less than (J) .....:		**900**		
Part or component tested	**Measured power dissipated (W)**	**Calculated energy dissipated (J)**	**SINGLE FAULT CONDITIONS waived (Yes/No)**	**Remarks**

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Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information:

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

13.2	TABLE: SINGLE FAULT CONDITIONS in accordance with 13.2.2 to 13.2.13, inclusive		P
Clause No.	**Description of SINGLE FAULT CONDITION**	**Results observed**	**HAZARDOUS SITUATION (Yes/No)**
13.2.2	**Electrical SINGLE FAULT CONDITIONS per Cl. 8.1:**	—	—
	Model GTM96600-6554-TP3	-	-
	264V/50Hz, max. normal load	-	-
	MOV1 short circuit	After SC, Fuse F1, F2 opened immediately.	No
	LF1 short circuit	After SC, the unit normal operation, No hazard	No
	CX1 short circuit	After SC, Fuse F1, F2 opened immediately.	No
	BD1 (pin 1-2) short circuit	After SC, the unit normal operation, No hazard	No
	D6 short circuit	After SC, the unit normal operation, No hazard	No
	T1 pin 1 - pin 3 short	After SC, Fuse F1, F2 opened immediately.	No
	T1 pin 4 - pin 5 short	After SC, Fuse F1, F2 opened immediately.	No
	Q1 pin D - pin S	After SC, Fuse F1, F2 opened immediately.	No
	Q1 pin D - pin G	After SC, Fuse F1, F2 opened immediately.	No
	Q1 pin S - pin G	After SC, The unit normal operation, No hazard	No
	R16A short	After SC, the unit normal operation, No hazard	No
	U4 pin 1 - pin 2 short	After SC, Fuse F1, F2 opened immediately.	No
	U4 pin 3 - pin 4 short	After SC, Fuse F1, F2 opened immediately.	No
	U4 pin 1 open	After SC, the unit shutdown, No hazard.	No
	U4 pin 3 open	After SC, the unit shutdown, No hazard.	No
	U1 pin 8 - pin 2 short	After SC, the unit normal operation, No hazard	No
	U1 pin 8 - pin 6 short	After SC, the unit normal operation, No hazard	No
	U1 pin 8 - pin 5 short	After SC, The unit normal operation, No hazard	No
	Model GTM96600-6554-TP3	-	No

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Clause	Requirement + Test	Result - Remark	Verdict

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
	Output S/C	After SC, Output shut down immediately. And recoverable after the fault condition removed	No
	Output S/C	After SC, Output shut down immediately. And recoverable after the fault condition removed	No
	Output Overload	Temperature test result see table 11	No
	Model GTM96600-4005-TP3 Q2 pin S - pin 2 short	After SC, the unit shutdown, No hazard.	No
13.2.3	**Overheating of transformers per Clause 15.5:**	—	—
	-		
13.2.4	**Failure of THERMOSTATS according to 13.2.13 & 15.4.2, overloading - THERMOSTATS short circuited or interrupted, the less favourable of the two:**	—	—
	-		
13.2.5	**Failure of temperature limiting devices according to 13.2.13 & 15.4.2, overloading, THERMOSTATS short circuited or interrupted, the less favourable of the two:**	—	—
	-		
13.2.6	**Leakage of liquid - RISK MANAGEMENT FILE examined to determine the appropriate test conditions (sealed rechargeable batteries exempted)**	—	—
	-		
13.2.7	**Impairment of cooling that could result in a HAZARD using test method of 11.1:**	—	—
	Single ventilation fans locked consecutively		
	Ventilation openings on top and sides impaired by covering openings on top of ENCLOSURE or positioning of ME EQUIPMENT against walls		
	Simulated blocking of filters		
	Flow of a cooling agent interrupted		

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Clause	Requirement + Test	Result - Remark	Verdict

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
13.2.8	Locking of moving parts – Only one part locked at a time – Also see 13.2.10 below:	—	—
	-		
13.2.9	Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited [1] – Also see 13.10	—	—
	-	V measured =	
		V measured =	
13.2.10	Additional test criteria for motor operated ME EQUIPMENT in 13.2.8 &13.2.9:	—	—
	For every test in SINGLE FAULT CONDITION of 13.2.8 and 13.2.9, motor-operated EQUIPMENT stared from COLD CONDITION at RATED voltage or upper limit of RATED voltage range for specified time:		
	Temperatures of windings determined at the end of specified test periods or at the instant of operation of fuses, THERMAL CUT-OUTS, motor protective devices		
	Temperatures measured as specified in 11.1.3 d)		
	Temperatures did not exceed limits of Table 26		
13.2.11	Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS:	—	—
	-		
13.2.12	Failure of parts that might result in a MECHANICAL HAZARD (See 9 & 15.3):	—	—
	-		

Supplementary information:

[1] Test with short-circuited capacitor not performed when motor provided with a capacitor complying with IEC 60252-1 and the ME EQUIPMENT not intended for unattended use including automatic or remote control. See Attachment # and appended Table 8.10.

Information from Risk Management, as applicable:

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Clause	Requirement + Test	Result - Remark	Verdict

15.3	TABLE: Mechanical Strength tests [1]		P
Clause	**Name of Test**	**Test conditions**	**Observed results/Remarks**
15.3.2	Push Test	Force = 250 N ± 10 N for 5 s Push on enclosure top / bottom / Side (Enclosure CX7211(GG))	For Model: GTM96600-6554-TP
15.3.2	Push Test	Force = 250 N ± 10 N for 5 s Push on enclosure top / bottom / Side (Enclosure 945(GG))	For Model: GTM96600-6019-T3
15.3.3	Impact Test	Steel ball (50 mm in dia., 500 g ± 25 g) falling from a 1.3 m Impact on enclosure top / bottom / Side (Enclosure CX7211(GG))	For Model: GTM96600-6554-TP
15.3.3	Impact Test	Steel ball (50 mm in dia., 500 g ± 25 g) falling from a 1.3 m Impact on enclosure top / bottom / Side (Enclosure 945(GG))	For Model: GTM96600-6019-T3
15.3.4.1	Drop Test (hand-held)	Free fall height (m) =	N/A
15.3.4.2	Drop Test (portable)	Drop height (cm) = 5 cm Drop on enclosure top / bottom / Side (Enclosure CX7211(GG))	For Model: GTM96600-6554-TP
15.3.4.2	Drop Test (portable)	Drop height (cm) = 5 cm Drop on enclosure top / bottom / Side (Enclosure 945(GG))	For Model: GTM96600-6019-T3
15.3.5	Rough handling test	Travel speed (m/s) =	N/A
15.3.6	Mould Stress Relief	7 h in oven at temperature (°C) = 107 (Enclosure CX7211(GG))	For Model: GTM96600-6554-TP
15.3.6	Mould Stress Relief	7 h in oven at temperature (°C) = 107 (Enclosure 945(GG))	For Model: GTM96600-6019-T3
Supplementary information: [1] As applicable, Push, Impact, Drop, Mould Stress Relief and Rough Handling Tests (delete not applicable rows or state N/A in Remarks field).			

15.4.6	TABLE: actuating parts of controls of ME EQUIPMENT – torque & axial pull tests				N/A
Rotating control under test	**Gripping diameter "d" of control knob (mm)[1]**	**Torque from Table 30 (Nm)**	**Axial force applied (N)**	**Unacceptable RISK occurred Yes/No**	**Remarks**
Supplementary information: [1] Gripping diameter (d) is the maximum width of a control knob regardless of its shape (e.g. control knob with pointer)					

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Clause	Requirement + Test	Result - Remark	Verdict

15.5.1.2	TABLE: transformer short circuit test short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION		P
Primary voltage (most adverse value from 90 % to 110 % of RATED voltage)(V)[1)]....:		85V / 264V	—
RATED input frequency (Hz) ....:		60 / 50	—

Winding tested	Class of insulation (A, B, E, F, or H)	Type of protective device (fuse, circuit breaker) /Ratings	Protective device operated Yes/No	Time to THERMAL STABILITY (when protective device did not operate)(Min)	Maximum allowed temp from Table 31 (°C)	Maximum winding temp measured (°C)	Ambient (°C)
Model: GTM96600-4005-TP3	-	-	-	-	-	-	-
T1 pin A - pin B	B	current limiting circuit	Yes	-	-	-	-
T1 pin 7 - pin 12	B	current limiting circuit	Yes	-	-	-	-
Model: GTM96600-6554-TP3EU	-	-	-	-	-	-	-
T1 pin A - pin B	B	current limiting circuit	Yes	-	-	-	-
T1 pin 7 - pin 12	B	current limiting circuit	Yes	-	-	-	-

Supplementary information:
[1)] Loads on other windings between no load and their NORMAL USE load. Short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION.

15.5.1.3	TABLE: transformer overload test – conducted only when protective device under short-circuit test operated	P
Primary voltage, most adverse value between 90 % to 110 % of RATED voltage (V)[1)] ..... :		See below
RATED input frequency (Hz) ..... :		SEE BELOW
Test current just below minimum current that would activate protective device and achieve THERMAL STABILITY under method a) (A) ..... :		SEE BELOW
Test current based on Table 32 when protective device that operated under method a) is external to transformer, and it was shunted (A) ..... :		-

Winding tested	Class of insulation (A, B, E, F, H)	Type of protective device used (fuse, circuit breaker)/Ratings	Maximum allowed temp from Table 31 (°C)	Maximum winding temp measured (°C)	Ambient (°C)
GTM96600-4005-TP3 (T1 pin A - B overload (between C14) (label down)	-	-	-	-	-
T1 pin A - pin B	B	current limiting circuit	165	See table 11.1.1	See table 11.1.1

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Clause	Requirement + Test	Result - Remark	Verdict

GTM96600-6554-TP3 (T1 pin A - B overload (between C14) (with insulator and copper foil) (label down)	-	-	-	-	-
T1 pin A - pin B	**B**	**current limiting circuit**	**165**	**See table 11.1.1**	**See table 11.1.1**

Supplementary information:
[1)] Loads on other windings between no load and their NORMAL USE load.
Time durations: - IEC 60127-1 fuse: 30 min at current from Table 32.
Non IEC 60127-1 fuse: 30 min at the current based on characteristics supplied by fuse manufacturer, specifically, 30 min clearing-time current. When no 30 min clearing-time current data available, test current from Table 32 used until THERMAL STABILITY achieved.
- Other types of protective devices: until THERMAL STABILITY achieved at a current just below minimum current operating the protective device in a). This portion concluded at specified time or when a second protective device opened.

15.5.2	TABLE: Transformer dielectric strength after humidity preconditioning of 5.7				N/A
Transformer Model/Type/ Part No	**Test voltage applied between**	**Test voltage, (V)**	**Test frequency (Hz)**	**Breakdown Yes/No**	**Deterioration Yes/No**
	Primary & secondary windings				
	Primary winding & frame				
	Secondary winding & frame				

Supplementary information: Tests conducted under the conditions of 11.1, in ME EQUIPMENT or under simulated conditions on the bench. See Clause 15.5.2 for test parameters & other details

16.6.1	TABLE: LEAKAGE CURRENTS in ME SYSTEM _ TOUCH CURRENT MEASUREMENTS			N/A
Specific area where TOUCH CURRENT measured (i.e., from or between parts of ME SYSTEM within PATIENT ENVIRONMENT)	**Allowable TOUCH CURRENT in NORMAL CONDITION (μA)**	**Measured TOUCH CURRENT in NORMAL CONDITION (μA)**	**Allowable TOUCH CURRENT in event of interruption of PROTECTIVE EARTH CONDUCTOR, (μA)**	**Measured TOUCH CURRENT in event of interruption of PROTECTIVE EARTH CONDUCTOR, (μA)**
	100		**500**	
	100		**500**	
	100		**500**	
	100		**500**	
	100		**500**	

Supplementary information:

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Clause	Requirement + Test	Result - Remark	Verdict

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

SP	TABLE: Additional or special tests conducted		P
Clause and Name of Test	**Test type and condition**	**Observed results**	
5.7 Humidity conditioning	Type test, RH: 93%, Temp.: 30 degree C, duration: 168h Parts under test: 1) GTM96600-6554-TP3EU (F3 insulation construction) 2) TIW, type: THL-F-xx, MFR: HOI LUEN ELECTRICAL MFR CO LTD 3) TIW, type: TRW(B) MFR: Great Leoflon Industrial Co Ltd 4) Transformer (T1), type TF061 MFR : GLOBTEK INC / WUXI HAOPUWEI ELECTRONICS CO LTD 5) Insulation tape on HS1, type 1350F-1, 1350T-1 MFR: 3M COMPANY ELECTRICAL MARKETS DIV (EMD) 6) Insulation tape on HS1, type: PZ, CT MFR: JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CO LTD 7) Insulation tape on HS1, type: JY25-A MFR: JINGJIANG JINGYI ADHESIVE PRODUCT CO LTD 8) Insulation tape on HS1, type: 370S MFR: BONDTEC PACIFIC CO LTD 9) Insulation tape on HS1, type: LY-XX* MFR: CHANG SHU LIANG YI TAPE INDUSTRY CO LTD 10) Insulator (only for hybrid desktop housing models), type FORMEX GK-(a)(d)(f2) MFR: FORMEX / ITW Materials Technology (Shanghai) Co.,LTD 11) Insulator (only for hybrid desktop housing models), type KLX PP BK-10 series, KLX PP BK-17, KLX PP WT-10 series MFR: CHENGDU KANGLONGXIN PLASTICS CO LTD 12) Insulator (only for hybrid desktop housing models), type PP-(i)(j) MFR: Sichuan Longhua Film Co Ltd 13) Insulator (only for hybrid desktop housing models), type EFR95(yy) MFR: F&S China Co., Ltd.	No hazard, no damage after dielectric voltage test.	

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Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information:

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Clause	Requirement + Test	Result - Remark	Verdict

SP	TABLE: Additional or special tests conducted		N/A
Clause and Name of Test	**Test type and condition**	**Observed results**	

Supplementary information:

This table is used to identify test results for tests other than referenced in the above test tables. Refer to Appendix B for all tests performed within this report.

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Clause	Requirement + Test	Result - Remark	Verdict

	Attachment - Software – IEC 62304:2006+AMD1:2015		—
62304: 4.3	**[A, B, C] Software safety classification**		N/A
	a) The manufacturer assigns to each software system a software safety class according to the risk of harm to the patient, operator, or other people resulting from a hazardous situation to which the software system can contribute in a worst-case-scenario		N/A
	The software system is software safety class A if:		N/A
	– the software system not contribute to a hazardous situation; or		N/A
	– the software system contribute to a hazardous situation which does not result in unacceptable risk after consideration of risk control measures external to the software system		N/A
	The software system is software safety class B if:		N/A
	– the software system contribute to a hazardous situation which results in unacceptable risk after consideration of risk control measures external to the software system and the resulting possible harm is non-serious injury		N/A
	The software system is software safety class C if:		N/A
	– the software system contribute to a hazardous situation which results in unacceptable risk after consideration of risk control measures external to the software system and the resulting possible harm is death or serious injury		N/A
	For a software system initially classified as software safety class B or C, the manufacturer has implemented additional risk control measures external to the software system and subsequently has assigned a new software safety classification to the software system		N/A
	c) The manufacturer documents the software safety class assigned to each software system in the risk management file		N/A
	d) When a software system is decomposed into software items, and when a software item is decomposed into further software items, such software items inherit the software safety classification of the original software item (or software system) unless the manufacturer documents a rationale for classification into a different software safety class		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

	Attachment - Software – IEC 62304:2006+AMD1:2015		—
	A rationale explains how the new software items are segregated so that they may be classified separately		N/A
	e) The manufacturer documents the software safety class of each software item if that class is different from the class of the software item from which it was created by decomposition		N/A
	f) When applied to a group of software items, the manufacturer uses the processes and tasks which are required by the classification of the highest-classified software item in the group unless the manufacturer documents in the risk management file a rationale for using a lower classification		N/A
	g) Class C requirements apply for each software system, until a software safety class is assigned		N/A
62304: 4.4	**[A, B, C] Legacy software**		N/A
	Clauses 5 through 9 have applied to demonstrate the compliance of legacy software		N/A
	As alternative, clauses 4.4.2 through 4.4.5 have applied to demonstrate the compliance of legacy software		N/A
62304: 4.4.2	**[A, B, C] Risk management activities**		N/A
	The manufacturer:		N/A
	a) assesses any feedback, including post-production information, on legacy software regarding incidents and / or near incidents, both from inside its own organization and / or from users		N/A
	b) performs risk management activities associated with continued use of the legacy software		N/A
	Considering the following aspects:		N/A
	– integration of the legacy software in the overall medical device architecture		N/A
	– continuing validity of risk control measures, implemented as part of the legacy software		N/A
	– identification of hazardous situations associated with the continued use of the legacy software		N/A
	– identification of potential causes of the legacy software contributing to a hazardous situations		N/A

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	Attachment - Software – IEC 62304:2006+AMD1:2015		—
	– definition of risk control measures for each potential cause of the legacy software contributing to a hazardous situations		N/A
62304: 4.4.3	**[A, B, C] Gap analysis**		N/A
	Based on the software safety class of the legacy software, the manufacturer performs a gap analysis of available deliverables against those required according to 5.2, 5.3, 5.7, and Clause 7		N/A
	a) The manufacturer assesses the continuing validity of available deliverables		N/A
	b) Where gaps are identified, the manufacturer evaluates the potential reduction in risk resulting from the generation of the missing deliverables and associated activities		N/A
	c) Based on this evaluation, the manufacturer determines the deliverables to be created and associated activities to be performed		N/A
	Software system test records are the minimum deliverables to be created		N/A
62304: 4.4.4	**[A, B, C] Gap closure activities**		N/A
	a) The manufacturer establishes and executes a plan to generate the identified deliverables		N/A
	Objective evidences have used to generate required deliverables without performing activities required by 5.2, 5.3, 5.7 and Clause 7		N/A
	b) The plan addresses the use of the problem resolution process for handling problems detected in the legacy software and deliverables in accordance with Clause 9		N/A
	c) Changes to the legacy software have performed in accordance with Clause 6.		N/A
62304: 4.4.5	**[A, B, C] Rationale for use of legacy software**		N/A
	The manufacturer documents the version of the legacy software together with a rationale for the continued use of the legacy software		N/A
62304: 5	**SOFTWARE DEVELOPMENT PROCESS**		N/A
62304: 5.1	**Software development planning**		N/A

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	Attachment - Software – IEC 62304:2006+AMD1:2015		—
62304: 5.1.1	**[A, B, C] The manufacturer establishes a software development plan (or plans) for conducting the activities of the software development process appropriate to the scope, magnitude, and software safety classifications of the software system to be developed.**		N/A
	The software development life cycle model is either fully defined or be referenced in the plan (or plans).		N/A
	The plan addresses the following:		N/A
	a) the processes to be used in the development of the software system		N/A
	b) the deliverables (includes documentation) of the activities and tasks		N/A
	c) traceability between system requirements, software requirements, software system test, and risk control measures implemented in software		N/A
	d) software configuration and change management, including soup configuration items and software used to support development		N/A
	e) software problem resolution for handling problems detected in the medical device software, deliverables and activities at each stage of the life cycle		N/A
62304: 5.1.2	**[A, B, C] The manufacturer updates the plan, as appropriate, as development proceeds**		N/A
62304: 5.1.3	**[A, B, C] Software development plan reference to system design and development**		N/A
	a) As inputs for software development, system requirements are referenced in the software development plan by the manufacturer		N/A
	b) In the software development plan, the manufacturer includes or references procedures for coordinating the software development with the system development necessary to satisfy 4.1 (such as system integration, verification, and validation)		N/A
62304: 5.1.4	**[C] Associated with the development of software items of class C, in the software development plan are included or referenced:**		N/A
	a) standards		N/A
	b) methods		N/A
	c) tools		N/A

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	Attachment - Software – IEC 62304:2006+AMD1:2015		—
62304: 5.1.5	**[B, C] The manufacturer includes or references in the software development plan, a plan to integrate the software items (including soup) and performs testing during integration**		N/A
62304: 5.1.6	**[A, B, C] In the software development plan, the following verification information are included or referenced:**		N/A
	a) deliverables requiring verification		N/A
	b) the required verification tasks for each life cycle activity		N/A
	c) milestones at which the deliverables are verified		N/A
	d) the acceptance criteria for verification of the deliverables		N/A
62304: 5.1.7	**[A, B, C] In the software development plan the manufacturer includes or references a plan to conduct the activities and tasks of the software risk management process, including the management of risks relating to soup**		N/A
62304: 5.1.8	**[A, B, C] In the software development plan the manufacturer includes or references information about the documents to be produced during the software development life cycle**		N/A
	For each identified document or type of document the following information has included or referenced:		N/A
	a) title, name or naming convention		N/A
	b) purpose		N/A
	c) procedures and responsibilities for development, review, approval and modification		N/A
62304: 5.1.9	**[A, B, C] The manufacturer includes or references software configuration management information in the software development plan**		N/A
	The software configuration management information includes or references:		N/A
	a) the classes, types, categories or lists of items to be controlled		N/A
	b) the software configuration management activities and tasks		N/A
	c) the organization(s) responsible for performing software configuration management and activities		N/A
	d) their relationship with other organizations, such as software development or maintenance		N/A

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	Attachment - Software – IEC 62304:2006+AMD1:2015		—
	e) when the items are to be placed under configuration control		N/A
	f) when the problem resolution process is to be used		N/A
62304: 5.1.10	**[B, C] The items to be controlled include tools, items or settings, used to develop the medical device software, which could impact the medical device software**		N/A
62304: 5.1.11	**[B, C] The manufacturer plans to place configuration items under documented configuration management control before they are verified**		N/A
62304: 5.1.12	**[B, C] In the software development plan the manufacturer includes or references a procedure for:**		N/A
	a) identifying categories of defects that may be introduced based on the selected programming technology that are relevant to their software system		N/A
	b) documenting evidence that demonstrates that these defects do not contribute to unacceptable risk		N/A
62304: 5.2	**Software requirements analysis**		N/A
62304: 5.2.1	**[A, B, C] For each software system of the medical device, the manufacturer defines and documents software system requirements from the system level requirements**		N/A
62304: 5.2.2	**[A, B, C] As appropriate to the medical device software, the manufacturer includes in the software requirements:**		N/A
	a) functional and capability requirements		N/A
	b) software system inputs and outputs		N/A
	c) interfaces between the software system and other systems		N/A
	d) software-driven alarms, warnings, and operator messages		N/A
	e) security requirements		N/A
	f) user interface requirements implemented by software		N/A
	g) data definition and database requirements		N/A
	h) installation and acceptance requirements of the delivered medical device software at the operation and maintenance site or sites		N/A
	i) requirements related to methods of operation and maintenance		N/A

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	Attachment - Software – IEC 62304:2006+AMD1:2015		—
	j) requirements related to IT-network aspects		N/A
	k) user maintenance requirements		N/A
	l) regulatory requirements		N/A
62304: 5.2.3	**[B, C] The manufacturer includes risk control measures implemented in software in the requirements as appropriate to the medical device software**		N/A
62304: 5.2.4	**[A, B, C] The manufacturer re-evaluates the medical device risk analysis when software requirements are established and update it as appropriate**		N/A
62304: 5.2.5	**[A, B, C] The manufacturer ensures that existing requirements, including system requirements, are re-evaluated and updated as appropriate as a result of the software requirements analysis activity**		N/A
62304: 5.2.6	**[A, B, C] The manufacturer verifies and documents that the software requirements:**		N/A
	a) implement system requirements including those relating to risk control		N/A
	b) do not contradict one another		N/A
	c) are expressed in terms that avoid ambiguity		N/A
	d) are stated in terms that permit establishment of test criteria and performance of tests		N/A
	e) can be uniquely identified		N/A
	f) are traceable to system requirements or other source		N/A
62304: 5.3	**Software architectural design**		N/A
62304: 5.3.1	**[B, C] The manufacturer transforms the requirements for the medical device software into a documented architecture that describes the software's structure and identifies the software items**		N/A
62304: 5.3.2	**[B, C] The manufacturer develops and documents an architecture for the interfaces between the software items and the components external to the software items (both software and hardware), and between the software items**		N/A
62304: 5.3.3	**[B, C] If a software item is identified as soup, the manufacturer specifies functional and performance requirements for the soup item that are necessary for its intended use**		N/A

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	Attachment - Software – IEC 62304:2006+AMD1:2015		—
62304: 5.3.4	**[B, C] If a software item is identified as soup, the manufacturer specifies the system hardware and software necessary to support the proper operation of the soup item**		N/A
62304: 5.3.5	**[C] The manufacturer identifies any segregation between software items that is necessary for risk control, and states how to ensure that such segregation is effective**		N/A
62304: 5.3.6	**[B, C] The manufacturer verifies and documents that:**		N/A
	a) the architecture of the software implements system and software requirements including those relating to risk control		N/A
	b) the software architecture is able to support interfaces between software items and between software items and hardware		N/A
	c) the medical device architecture supports proper operation of any soup items		N/A
62304: 5.4	**Software detailed design**		N/A
62304: 5.4.1	**[B, C] The manufacturer subdivides the software until it is represented by software units**		N/A
62304: 5.4.2	**[C] The manufacturer documents a design with enough detail to allow correct implementation of each software unit**		N/A
62304: 5.4.3	**[C] The manufacturer documents a design for any interfaces between the software unit and external components (hardware or software), as well as any interfaces between software units, detailed enough to implement each software unit and its interfaces correctly**		N/A
62304: 5.4.4	**[C] The manufacturer verifies and documents that the software detailed design:**		N/A
	a) implements the software architecture		N/A
	b) is free from contradiction with the software architecture		N/A
62304: 5.5	**Software unit implementation**		N/A
62304: 5.5.1	**[A, B, C] The manufacturer implements each software unit**		N/A
62304: 5.5.2	**[B, C] The manufacturer establishes strategies, methods and procedures for verifying the software units**		N/A
	Where verification is done by testing, the test procedures are evaluated for adequacy		N/A

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	Attachment - Software – IEC 62304:2006+AMD1:2015		—
62304: 5.5.3	**[B, C] The manufacturer establishes acceptance criteria for software units prior to integration into larger software items as appropriate, and ensures that software units meet acceptance criteria**		N/A
62304: 5.5.4	**[C] When present in the design, the manufacturer includes additional acceptance criteria as appropriate for:**		N/A
	a) proper event sequence		N/A
	b) data and control flow		N/A
	c) planned resource allocation		N/A
	d) fault handling (error definition, isolation, and recovery)		N/A
	e) initialisation of variables		N/A
	f) self-diagnostics		N/A
	g) memory management and memory overflows		N/A
	h) boundary conditions		N/A
62304: 5.5.5	**[B, C] The manufacturer performs the software unit verification and documents the results**		N/A
62304: 5.6	**Software integration and integration testing**		N/A
62304: 5.6.1	**[B, C] The manufacturer integrates the software units in accordance with the integration plan**		N/A
62304: 5.6.2	**[B, C] The manufacturer verifies that the software units have been integrated into software items and/or the software system in accordance with the integration plan and retains records of the evidence of such verification**		N/A
62304: 5.6.3	**[B, C] The manufacturer tests the integrated software items in accordance with the integration plan and documents the results**		N/A
62304: 5.6.4	**[B, C] For software integration testing, the manufacturer addresses whether the integrated software item performs as intended**		N/A
62304: 5.6.5	**[B, C] The manufacturer evaluates the integration test procedures for adequacy**		N/A
62304: 5.6.6	**[B, C] When software items are integrated, the manufacturer conducts regression testing appropriate to demonstrate that defects have not been introduced into previously integrated software**		N/A
62304: 5.6.7	**[B, C] The manufacturer:**		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

	Attachment - Software – IEC 62304:2006+AMD1:2015		—
	a) documents the test result (pass/fail and a list of anomalies)		N/A
	b) retains sufficient records to permit the test to be repeated		N/A
	c) identifies the tester		N/A
62304: 5.6.8	**[B, C] The manufacturer enters anomalies found during software integration and integration testing into a software problem resolution process**		N/A
62304: 5.7	**Software system testing**		N/A
62304: 5.7.1	**[A, B, C] Establish tests for software requirements**		N/A
	a) The manufacturer establishes and performs a set of tests, expressed as input stimuli, expected outcomes, pass/fail criteria and procedures, for conducting software system testing, such that all software requirements are covered		N/A
	b) The manufacturer evaluates the adequacy of verification strategies and test procedures.		N/A
62304: 5.7.2	**[A, B, C] The manufacturer enters anomalies found during software system testing into a software problem resolution process**		N/A
62304: 5.7.3	**[A, B, C] When changes are made during software system testing, the manufacturer:**		N/A
	a) repeats tests, performs modified tests or performs additional tests, as appropriate, to verify the effectiveness of the change in correcting the problem		N/A
	b) conducts testing appropriate to demonstrate that unintended side effects have not been introduced		N/A
	c) performs relevant risk management activities as defined in 7.4		N/A
62304: 5.7.4	**[A, B, C] Evaluate software system testing**		N/A
	The manufacturer evaluates the appropriateness of verification strategies and test procedures		N/A
	The manufacturer verifies that:		N/A
	a) all software requirements have been tested or otherwise verified		N/A

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	Attachment - Software – IEC 62304:2006+AMD1:2015		—
	b) the traceability between software requirements and tests or other verification is recorded		N/A
	c) test results meet the required pass/fail criteria		N/A
62304: 5.7.5.	**[A, B, C] In order to support the repeatability of tests, the manufacturer documents:**		N/A
	a) a reference to test case procedures showing required actions and expected results		N/A
	b) the test result (pass/fail and a list of anomalies)		N/A
	c) the version of software tested		N/A
	d) relevant hardware and software test configurations		N/A
	e) relevant test tools		N/A
	f) date tested		N/A
	g) the identity of the person responsible for executing the test and recording the test results		N/A
62304: 5.8	**Software release for utilization at a system level**		N/A
62304: 5.8.1	**[A, B, C] The manufacturer ensures that all software verification activities has been completed and the results evaluated before the software is released**		N/A
62304: 5.8.2	**[A, B, C] The manufacturer documents all known residual anomalies**		N/A
62304: 5.8.3	**[B, C] The manufacturer ensured that all known residual anomalies have been evaluated to ensure that they do not contribute to an unacceptable risk**		N/A
62304: 5.8.4	**[A, B, C] The manufacturer documented the version of the medical device software that is being released**		N/A
62304: 5.8.5	**[B, C] The manufacturer documents the procedure and environment used to create the released software**		N/A
62304: 5.8.6	**[B, C] The manufacturer ensures that all software development plan (or maintenance plan) activities and tasks are complete along with the associated documentation**		N/A
62304: 5.8.7	**[A, B, C] For at least a period of time determined as the longer of: the life time of the medical device software as defined by the manufacturer or a time specified by relevant regulatory requirements, the manufacturer archives:**		N/A

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	Attachment - Software – IEC 62304:2006+AMD1:2015		—
	a) the medical device software and configuration items		N/A
	b) the documentation		N/A
62304: 5.8.8	**[A, B, C] The manufacturer establishes procedures to ensure that the released medical device software can be reliably delivered to the point of use without corruption or unauthorised change**		N/A
	These procedures address the production and handling of media containing the medical device software including as appropriate:		N/A
	– replication		N/A
	– media labelling		N/A
	– packaging		N/A
	– protection		N/A
	– storage		N/A
	– delivery		N/A
62304: 7	**SOFTWARE RISK MANAGEMENT PROCESS**		N/A
62304: 7.1	**Analysis of software contributing to hazardous situations**		N/A
62304: 7.1.1	**[B, C] The manufacturer identifies software items that could contribute to a hazardous situation identified in the medical device risk analysis activity of ISO 14971**		N/A
62304: 7.1.2	**[B, C] The manufacturer identifies potential causes of the software item identified above contributing to a hazardous situation**		N/A
	The manufacturer considers potential causes including, as appropriate:		N/A
	a) incorrect or incomplete specification of functionality		N/A
	b) software defects in the identified software item functionality		N/A
	c) failure or unexpected results from soup		N/A
	d) hardware failures or other software defects that could result in unpredictable software operation		N/A
	e) reasonably foreseeable misuse		N/A

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	Attachment - Software – IEC 62304:2006+AMD1:2015		—
62304: 7.1.3	**[B, C] If failure or unexpected results from soup is a potential cause of the software item contributing to a hazardous situation, the manufacturer evaluates as a minimum any anomaly list published by the supplier of the soup item relevant to the version of the soup item used in the medical device to determine if any of the known anomalies result in a sequence of events that could result in a hazardous situation**		N/A
62304: 7.1.4	**[B, C] The manufacturer documents in the risk management file potential causes of the software item contributing to a hazardous situation**		N/A
62304: 7.2	**Risk control measures**		N/A
62304: 7.2.1	**[B, C] For each case documented in the risk management file where a software item could contribute to a hazardous situation, the manufacturer defines and documents risk control measures in accordance with ISO 14971**		N/A
62304: 7.2.2	**[B, C] If a risk control measure is implemented as part of the functions of a software item, the manufacturer:**		N/A
	a) includes the risk control measure in the software requirements		N/A
	b) assigns to each software item that contributes to the implementation of a risk control measure a software safety class based on the risk that the risk control measure is controlling		N/A
	c) develops the software item in accordance with Clause 5		N/A
62304: 7.3	**Verification of risk control measures**		N/A
62304: 7.3.1	**[B, C] The implementation of each risk control measure documented in 7.2 is verified, and this verification is documented**		N/A
	The manufacturer reviewers the risk control measure and determines if it could result in a new hazardous situation		N/A
62304: 7.3.3	**[B, C] The manufacturer documents traceability of software hazards as appropriate:**		N/A
	a) from the hazardous situation to the software item		N/A
	b) from the software item to the specific software cause		N/A

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	Attachment - Software – IEC 62304:2006+AMD1:2015		—
	c) from the software cause to the risk control measure		N/A
	d) from the risk control measure to the verification of the risk control measure		N/A
62304: 7.4	**Risk management of software changes**		N/A
62304: 7.4.1	**[A, B, C] The manufacturer analyses changes to the medical device software (including soup) to determine whether:**		N/A
	a) additional potential causes are introduced contributing to a hazardous situation		N/A
	b) additional software risk control measures are required		N/A
62304: 7.4.2	**[B, C] The manufacturer analyses changes to the software, including changes to soup, to determine whether the software modification could interfere with existing risk control measures**		N/A
62304: 7.4.3	**[B, C] The manufacturer performs relevant risk management activities defined in 7.1, 7.2 and 7.3 based on these analyses**		N/A
62304: 8	**SOFTWARE CONFIGURATION MANAGEMENT PROCESS**		N/A
62304: 8.1	**Configuration identification**		N/A
62304: 8.1.1	**[A, B, C] The manufacturer establishes a scheme for the unique identification of configuration items and their versions to be controlled according to the development and configuration planning specified in 5.1**		N/A
62304: 8.1.2	**[A, B, C] For each soup configuration item being used, including standard libraries, the manufacturer documents:**		N/A
	a) the title		N/A
	b) the manufacturer		N/A
	c) the unique soup designator		N/A
62304: 8.1.3	**[A, B, C] The manufacturer documents the set of configuration items and their versions that comprise the software system configuration**		N/A
62304: 8.2	**Change control**		N/A
62304: 8.2.1	**[A, B, C] The manufacturer changes configuration items identified to be controlled according to 8.1 only in response to an approved change request**		N/A
62304: 8.2.2	**[A, B, C] The manufacturer implements the change as specified in the change request**		N/A

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	Attachment - Software – IEC 62304:2006+AMD1:2015		—
	The manufacturer identifies and performs any activity that needs to be repeated as a result of the change, including changes to the software safety classification of software systems and software items		N/A
62304: 8.2.3	**[A, B, C] The manufacturer verifies the change, including repeating any verification that has been invalidated by the change and taking into account 5.7.3 and 9.7**		N/A
62304: 8.2.4	**[A, B, C] The manufacturer maintains records of the relationships and dependencies between:**		N/A
	a) change request		N/A
	b) relevant problem report		N/A
	c) approval of the change request		N/A
62304: 8.3	**[A, B, C] The manufacturer retains retrievable records of the history of controlled configuration items including system configuration**		N/A
62304: 9	**SOFTWARE PROBLEM RESOLUTION PROCESS**		N/A
62304: 9.1	**[A, B, C] The manufacturer prepares a problem report for each problem detected in the medical device software**		N/A
	Problem reports include a statement of criticality (for example, effect on performance, safety, or security) as well as other information that may aid in the resolution of the problem (for example, devices affected, supported accessories affected)		N/A
62304: 9.2	**[A, B, C] The manufacturer:**		N/A
	a) investigates the problem and if possible identify the causes		N/A
	b) evaluates the problem's relevance to safety using the software risk management process		N/A
	c) documents the outcome of the investigation and evaluation		N/A
	d) creates a change request(s) for actions needed to correct the problem, or document the rationale for taking no action		N/A
62304: 9.3	**[A, B, C] The manufacturer advises relevant parties of the existence of the problem, as appropriate**		N/A
62304: 9.4	**[A, B, C] The manufacturer approves and implements all change requests, observing the requirements of the change control process**		N/A

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	Attachment - Software – IEC 62304:2006+AMD1:2015		—
62304: 9.5	**[A, B, C] The manufacturer maintains records of problem reports and their resolution including their verification**		N/A
	The manufacturer updates the risk management file as appropriate		N/A
62304: 9.6	**[A, B, C] The manufacturer performs analysis to detect trends in problem reports**		N/A
62304: 9.7	**[A, B, C] The manufacturer verifies resolutions to determine whether:**		N/A
	a) problem has been resolved and the problem report has been closed		N/A
	b) adverse trends have been reversed		N/A
	c) change requests have been implemented in the appropriate medical device software and activities		N/A
	d) additional problems have been introduced		N/A
62304: 9.8	**[A, B, C] When testing, retesting or regression testing software items and systems following a change, the manufacturer includes in the test documentation:**		N/A
	a) test results		N/A
	b) anomalies found		N/A
	c) the version of software tested		N/A
	d) relevant hardware and software test configurations		N/A
	e) relevant test tools		N/A
	f) date tested		N/A
	g) identification of the tester		N/A

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Attachment	**Software - Mapping of required evidence and manufacturer documents**			—
Standard Clause	Deliverables	Title	Revision #	Date
4.3	Software safety classification document			
4.3	Specification of risk control measures external to software system			
4.3	Rationale of classification for decomposed software system			
4.4.2	Risk management activities for legacy software			
4.4.3	Gap analysis for legacy software			
4.4.4	Gap closure plan for legacy software			
4.4.5	Rationale for use of legacy software			
5.1.1	Software development plan			
5.1.3	Software requirements reference to software design and development document			
5.1.4	Development standards, methods and tools records for class C software			
5.1.5	Software integration and integration testing plan			
5.1.6	Software verification plan			
5.1.7	Software risk management plan			
5.1.8	Document management procedures			
5.1.9	Software configuration management procedures			
5.2	Software system requirements specification			
5.2.3	Specification of risk control measure implemented in software			
5.3	Software system architecture design specification			
5.3	Software item architecture design specification			
5.4	Software item detailed design specification			
5.4	Software unit detailed design specification			

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Clause	Requirement + Test	Result - Remark	Verdict

Attachment	**Software - Mapping of required evidence and manufacturer documents**			—
Standard Clause	Deliverables	Title	Revision #	Date
5.5.1	Software unit implementation records			
5.5.2	Software unit verification process			
5.5.3	Software unit acceptance criteria			
5.5.5	Software unit verification records			
5.6.1	Software unit integration process			
5.6.2	Software unit integration records			
5.6.4	Software unit integration testing records			
5.6.5	Evaluation of software unit integration test			
5.6.6	Software unit regression testing process			
5.6.7	Software unit regression testing records			
5.6.8	Software problem resolution process			
5.7	Software system testing process			
5.7	Software system testing records			
5.8	Software system release process			
5.8	Software system release record			
5.8	Statement of known residual anomalies			
7.1	Software hazard analysis process			
7.1	SOUP anomaly lists			
7.2	Risk control process			
7.3	Risk control verification process			
7.4	Risk management of software change process			
8.1	Configuration identification record			
8.2	Change control process			
8.2	Records for traceability of change			
9	Software problem resolution process			
9	Software problem resolution records			

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Attachment	**Software - Mapping of required evidence and manufacturer documents**			—
Standard Clause	Deliverables	Title	Revision #	Date

Supplementary information:

Supplementary information:

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Clause	Requirement + Test	Result - Remark	Verdict

8.10	**TABLE:** List of critical components	Pass

Object/ Part No.	Manufacturer/ Trademark	Type / model	Technical data	Standard [2]	Mark(s) of conformity [1]
Plastic Enclosure (for desktop model)	SABIC INNOVATIVE PLASTICS B V	CX7211(GG)	Rated min V-0, 90 degC. Overall around 117.5 by 53.5 by 34.2mm, min. 2.0 mm thick. See enclosure diagram-(001) for detail.	ANSI /UL 94/Ed.7 ANSI /UL 746B/Ed.5	UL/cUL (QMFZ2/8, E45329) --
Plastic Enclosure (for desktop model) (Alternate)	SABIC JAPAN L L C	CX7211(GG)	Rated min V-0, 90 degC. Overall around 117.5 by 53.5 by 34.2mm, min. 2.0 mm thick.	ANSI /UL 94/Ed.7 ANSI /UL 746B/Ed.5	UL (QMFZ2, E207780) --
Plastic Enclosure (for desktop model) (Alternate)	SABIC INNOVATIVE PLASTICS B V	945(GG)	Rated min V-0, 120 degC. Overall around 117.5 by 53.5 by 34.2mm, min. 2.0 mm thick.	ANSI /UL 94/Ed.7 ANSI /UL 746B/Ed.5	UL/cUL (QMFZ2/8, E45329) --
Plastic Enclosure (for desktop model) (Alternate)	SABIC JAPAN L L C	945(GG)	Rated min V-0, 120 degC. Overall around 117.5 by 53.5 by 34.2mm, min. 2.0 mm thick.	ANSI /UL 94/Ed.7 ANSI /UL 746B/Ed.5	UL/cUL (QMFZ2/8, E207780) --
Plastic Enclosure (for hybrid desktop housing model)	SABIC INNOVATIVE PLASTICS B V	CX7211(GG)	Rated min V-0, 120 degC. Overall around 114.6 by 54.1 by 36.6mm, min. 2.0 mm thick. See enclosure diagram-(002) for detail.	ANSI /UL 94/Ed.7 ANSI /UL 746B/Ed.5	UL/cUL (QMFZ2/8, E45329) --
Plastic Enclosure (for hybrid desktop housing model) (Alternate)	SABIC JAPAN L L C	CX7211(GG)	Rated min V-0, 120 degC. Overall around 114.6 by 54.1 by 36.6mm, min. 2.0 mm thick.	ANSI /UL 94/Ed.7 ANSI /UL 746B/Ed.5	UL (QMFZ2, E207780) --
Plastic Enclosure (for hybrid desktop housing model) (Alternate)	SABIC INNOVATIVE PLASTICS B V	945(GG)	Rated min V-0, 120 degC. Overall around 114.6 by 54.1 by 36.6mm, min. 2.0 mm thick.	ANSI /UL 94/Ed.7 ANSI /UL 746B/Ed.5	UL/cUL (QMFZ2/8, E45329) --
Plastic Enclosure (for hybrid desktop housing model) (Alternate)	SABIC JAPAN L L C	945(GG)	Rated min V-0, 120 degC. Overall around 114.6 by 54.1 by 36.6mm, min. 2.0 mm thick.	ANSI /UL 94/Ed.7 ANSI /UL 746B/Ed.5	UL/cUL (QMFZ2/8, E207780) --
Plastic Enclosure (for Encapsulated model)	SABIC INNOVATIVE PLASTICS B V	CX7211(GG)	Rated min V-0, 90 degC. Overall around 114.81 by 57.11 by 39mm, Min. 2.0 mm thick. See enclosure diagram-(003) for detail.	ANSI /UL 94/Ed.7 ANSI /UL 746B/Ed.5	UL/cUL (QMFZ2/8, E45329) --
Plastic Enclosure (for Encapsulated model) (Alternate)	SABIC JAPAN L L C	CX7211(GG)	Rated min V-0, 90 degC. Overall around 114.81 by 57.11 by 39mm, Min. 2.0 mm	ANSI /UL 94/Ed.7 ANSI /UL 746B/Ed.5	UL (QMFZ2, E207780) --

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8.10	**TABLE:** List of critical components				Pass
Object/ Part No.	Manufacturer/ Trademark	Type / model	Technical data	Standard [2]	Mark(s) of conformity [1]
			thick.		
Plastic Enclosure (for Encapsulated model) (Alternate)	SABIC INNOVATIVE PLASTICS B V	945(GG)	Rated min V-0, 90 degC. Overall around 114.81 by 57.11 by 39mm, Min. 2.0 mm thick.	ANSI /UL 94/Ed.7 ANSI /UL 746B/Ed.5	UL/cUL (QMFZ2/8, E45329) --
Plastic Enclosure (for Encapsulated model) (Alternate)	SABIC JAPAN L L C	945(GG)	Rated min V-0, 90 degC. Overall around 114.81 by 57.11 by 39mm, Min. 2.0 mm thick.	ANSI /UL 94/Ed.7 ANSI /UL 746B/Ed.5	UL/cUL (QMFZ2/8, E207780) --
Insulator (only for hybrid desktop housing models)	FORMEX	FORMEX GK-(a)(d)(f2)	Provided between PWB and Enclosure. Rated V-0, 115 degC. Overall measured 53 by 46.80mm or 60 by 46.5mm, 0.43 mm thick.	ANSI /UL 94/Ed.7 ANSI /UL 746B/Ed.5	UL (QMFZ2, E121855) --
Insulator (only for hybrid desktop housing models) (Alternate)	CHENGDU KANGLONGXIN PLASTICS CO LTD	KLX PP BK-10 series, KLX PP BK-17, KLX PP WT-10 series	Provided between PWB and Enclosure. Rated V-0, 105 degC. Overall measured 53 by 46.80mm or 60 by 46.5mm, 0.43 mm thick.	ANSI /UL 94/Ed.7 ANSI /UL 746B/Ed.5	UL (QMFZ2, E315185) --
Insulator (only for hybrid desktop housing models) (Alternate)	Sichuan Longhua Film Co Ltd	PP-(i)(j)	Provided between PWB and Enclosure. Rated V-0, 105 degC. Overall measured 53 by 46.80mm or 60 by 46.5mm, 0.43 mm thick.	ANSI /UL 94/Ed.7 ANSI /UL 746B/Ed.5	UL (QMFZ2, E254551) --
Insulator (only for hybrid desktop housing models) (Alternate)	ITW Materials Technology (Shanghai) Co.,LTD	FORMEX GK-(a)(d)(f2)	Provided between PWB and Enclosure. Rated V-0, 115 degC. Overall measured 53 by 46.80mm or 60 by 46.5mm, 0.43 mm thick.	ANSI /UL 94/Ed.7 ANSI /UL 746B/Ed.5	UL (QMFZ2, E256266) --
Insulator (only for hybrid desktop housing models) (Alternate)	F&S China Co., Ltd.	EFR95(yy)	Provided between PWB and Enclosure. Rated V-0, 130degC. Overall measured 53 by 46.80mm or 60 by 46.5mm, 0.43 mm thick.	ANSI /UL 94/Ed.7 ANSI /UL 746B/Ed.5	UL (QMFZ2, E539253) --
Appliance –Inlet (For T2, T2L, R2 series)	ZHEJIANG LECI ELECTRONICS CO LTD	DB-8	Rated 2.5A, 250Vac, standard sheet C8	-- DIN EN 60320-1 (VDE 0625-1):2021-08; EN 60320-1:2015+AC:2016+AC:2019+A1:2021 IEC 60320-1:2015IEC 60320-1:2015/AMD1:2018	-- VDE(40032028)

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Clause	Requirement + Test	Result - Remark	Verdict

8.10	**TABLE:** List of critical components				Pass
Object/ Part No.	Manufacturer/ Trademark	Type / model	Technical data	Standard [2]	Mark(s) of conformity [1]
Appliance –Inlet (For T2, T2L, R2 series) (Alternate)	Rong Feng Industrial Co.,Ltd	RF-180	Rated 2.5A, 250Vac, standard sheet C8	ANSI/UL 60320-1/ Ed.3 CAN/CSA-C22.2 No. 60320-1 DIN EN IEC 60320-1 (VDE 0625-1):2023-06; EN IEC 60320-1:2021 IEC 60320-1:2021	UL/cUL (AXUT2/8, E102641) VDE(40030168)
Appliance –Inlet (For T2, T2L, R2 series) (Alternate)	RICH BAY CO LTD	R-201SN90	Rated 2.5A, 250Vac, standard sheet C8	ANSI/UL 60320-1 /Ed.3 CAN/CSA-C22.2 No. 60320-1 DIN EN IEC 60320-1 (VDE 0625-1):2023-06; EN IEC 60320-1:2021 IEC 60320-1:2021	UL/cUL (AXUT2/8, E184638) VDE(40030384)
Appliance –Inlet (For T2, T2L, R2 series) (Alternate)	SUN FAIR ELECTRIC WIRE & CABLE (HK) CO LTD	S-01	Rated 2.5A, 250Vac. standard sheet C8	ANSI/UL 60320-1/ Ed.3 CAN/CSA-C22.2 No. 60320-1 DIN EN 60320-1 (VDE 0625-1):2016-04; EN 60320-1:2015 + AC:2016IEC 60320-1:2015	UL/cUL (AXUT2/8, E226643) VDE(40034449)
Appliance –Inlet (For T2, T2L, R2 series) (Alternate)	Zhe Jiang Bei Er Jia Electronic Co.,Ltd.	ST-A03 series	Rated 2.5A, 250Vac, standard sheet C8	ANSI/UL 60320-1 Ed.3 CAN/CSA-C22.2 No. 60320-1 DIN EN IEC 60320-1 (VDE 0625-1):2023-06; EN IEC 60320-1:2021 IEC 60320-1:2021	UL/cUL (AXUT2/8, E225980) VDE(40014833)
Appliance –Inlet (For T2, T2L, R2 series) (Alternate)	TECX-UNIONS TECHNOLOGY CORP	SO-222 series	Rated 2.5A, 250Vac, standard sheet C8	ANSI/UL 60320-1/ Ed.3 CAN/CSA-C22.2 No. 60320-1 EN IEC 60320-1:2021	UL/cUL (AXUT2/8, E220004) ENEC (ENEC-04808)
Appliance –Inlet (For T2, T2L, R2 series) (Alternate)	Interchangeable	Interchangeable	Rated 2.5A, 250Vac, standard sheet C8	--	-- --
Appliance –Inlet (For T2A, T2AL series)	HCR ELECTRONICS CO., LTD	SK05 series	Rated 10A, 250Vac, standard sheet C18	ANSI/UL 60320-1/ Ed.3 CAN/CSA-C22.2 No. 60320-1 EN 60320-1:2015	UL/cUL (AXUT2/8, E344254) ENEC (NO4018)
Appliance –Inlet (For T2A, T2AL series) (Alternate)	Rong Feng Industrial Co.,Ltd	SS-120	Rated 10A, 250Vac, standard sheet C18	ANSI/UL 60320-1/ Ed.3 CAN/CSA-C22.2 No. 60320-1DIN EN IEC 60320-1 (VDE 0625-1):2023-06; EN IEC 60320-1:2021 IEC 60320-1:2021	UL/cUL (AXUT2/8, E102641) VDE(40028101)
Appliance –Inlet (For T2A, T2AL series) (Alternate)	Rich Bay Co., Ltd.	R-301SN	Rated 10A, 250Vac, standard sheet C18	ANSI/UL 60320-1/ Ed.3 CAN/CSA-C22.2 No. 60320-1 DIN EN IEC 60320-1 (VDE 0625-1):2023-06; EN IEC 60320-1:2021 IEC 60320-1:2021	UL/cUL (AXUT2/8, E184638) VDE(40030228)
Appliance –Inlet	Interchangeable	Interchangeable	Rated 10A, 250Vac,	--	--

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8.10	**TABLE:** List of critical components				Pass
Object/ Part No.	Manufacturer/ Trademark	Type / model	Technical data	Standard [2]	Mark(s) of conformity [1]
(For T2A, T2AL series) (Alternate)			standard sheet C18		--
Appliance –Inlet (for T3A, T3AL, R3A series)	ZHEJIANG LECI ELECTRONICS CO LTD	DB-6	Rated 2.5A, 250Vac, standard sheet C6	ANSI/UL 60320-1/ Ed.3 CAN/CSA-C22.2 No. 60320-1 DIN EN 60320-1 (VDE 0625-1):2021-08; EN 60320-1:2015+AC:2016+AC:2019+A1:2021 IEC 60320-1:2015IEC 60320-1:2015/AMD1:2018	UL/cUL (AXUT2/8, E302229) VDE(40032465)
Appliance –Inlet (for T3A, T3AL, R3A series) (Alternate)	TECX-UNIONS TECHNOLOGY CORP	TU-333 series	Rated 2.5A, 250Vac, standard sheet C6	ANSI/UL 60320-1/ Ed.3 CAN/CSA-C22.2 No. 60320-1 EN IEC 60320-1:2021	UL/cUL (AXUT2/8, E220004) ENEC (ENEC-04682)
Appliance –Inlet (for T3A, T3AL, R3A series) (Alternate)	Rong Feng Industrial Co., Ltd.	RF-190	Rated 2.5A, 250Vac, standard sheet C6	ANSI/UL 60320-1/ Ed.3 CAN/CSA-C22.2 No. 60320-1 DIN EN IEC 60320-1 (VDE 0625-1):2023-06; EN IEC 60320-1:2021 IEC 60320-1:2021	UL/cUL (AXUT2/8, E102641) VDE(40030379)
Appliance –Inlet (for T3A, T3AL, R3A series) (Alternate)	RICH BAY CO LTD	R-30790, R-307	Rated 2.5A, 250Vac, standard sheet C6	ANSI/UL 60320-1/ Ed.3 CAN/CSA-C22.2 No. 60320-1 DIN EN IEC 60320-1 (VDE 0625-1):2023-06; EN IEC 60320-1:2021 IEC 60320-1:2021	UL/cUL (AXUT2/8, E184638) VDE(40030381)
Appliance –Inlet (for T3A, T3AL, R3A series) (Alternate)	Zhe Jiang Bei Er Jia Electronic Co.,Ltd.	ST-A04 series	Rated 2.5A, 250Vac, standard sheet C6	ANSI/UL 60320-1/ Ed.3 CAN/CSA-C22.2 No. 60320-1 DIN EN IEC 60320-1 (VDE 0625-1):2023-06; EN IEC 60320-1:2021 IEC 60320-1:2021	UL/cUL (AXUT2/8, E225980) VDE(40016045)
Appliance –Inlet (for T3A, T3AL, R3A series) (Alternate)	Interchangeable	Interchangeable	Rated 2.5A, 250Vac, standard sheet C6		-- --
Appliance –Inlet (for T3, T3L series)	LECI Electronics Co., Ltd.	DB-14	Rated 10A, 250Vac, standard sheet C14	ANSI/UL 60320-1/ Ed.3 CAN/CSA-C22.2 No. 60320-1 DIN EN IEC 60320-1 (VDE 0625-1):2023-06; EN IEC 60320-1:2021IEC 60320-1:2021	UL/cUL (AXUT2/8, E302229) VDE(40032137)
Appliance –Inlet (for T3, T3L series) (Alternate)	TECX-UNIONS Technology Corporation	TU-301 series	Rated 10A, 250Vac, standard sheet C14	ANSI/UL 60320-1/ Ed.3 CAN/CSA-C22.2 No. 60320-1 EN IEC 60320-1:2021	UL/cUL (AXUT2/8, E220004) ENEC (ENEC-04684)
Appliance –Inlet (for T3, T3L series)	Rich Bay Co., Ltd.	R-301SN	Rated 10A, 250Vac, standard sheet C14	ANSI/UL 60320-1/ Ed.3 CAN/CSA-C22.2 No. 60320-1	UL/cUL (AXUT2/8, E184638) VDE(40030228)

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8.10	**TABLE:** List of critical components				Pass
Object/ Part No.	Manufacturer/ Trademark	Type / model	Technical data	Standard [2]	Mark(s) of conformity [1]
(Alternate)				DIN EN IEC 60320-1 (VDE 0625-1):2023-06; EN IEC 60320-1:2021 IEC 60320-1:2021	
Appliance –Inlet (for T3, T3L series) (Alternate)	Rong Feng Industrial Co.,Ltd	SS-120	Rated 10A, 250Vac, standard sheet C14	ANSI/UL 60320-1/ Ed.3 CAN/CSA-C22.2 No. 60320-1 DIN EN IEC 60320-1 (VDE 0625-1):2023-06; EN IEC 60320-1:2021IEC 60320-1:2021	UL/cUL (AXUT2/8, E102641) VDE(40028101)
Appliance –Inlet (for T3, T3L series) (Alternate)	Zhe Jiang Bei Er Jia Electronic Co.,Ltd.	ST-A01 series	Rated 10A, 250Vac, standard sheet C14	ANSI/UL 60320-1/ Ed.3 CAN/CSA-C22.2 No. 60320-1 DIN EN IEC 60320-1 (VDE 0625-1):2023-06; EN IEC 60320-1:2021IEC 60320-1:2021	UL/cUL (AXUT2/8, E225980) VDE(40013388)
Appliance –Inlet (for T3, T3L series) (Alternate)	Interchangeable	Interchangeable	Rated 10A, 250Vac, standard sheet C14		-- --
Fuse (F1, F2)	ZHONG SHAN LANBAO ELECTRICAL APPLIANCES CO LTD	RTI-10 Serie	T3.15A 250V Breaking capacity: 50A	ANSI/UL 248-1/Ed.4 CSA-C22.2 No. 248.1 (2011) DIN EN 60127-1 (VDE 0820-1):2015-12; EN 60127-1:2006+A1:2011+A2:2015DIN EN 60127-3 (VDE 0820-3):2021-08; EN 60127-3:2015+A1:2020 IEC 60127-1:2006IEC 60127-1:2006/AMD1:2011IEC 60127-1:2006/AMD2:2015IEC 60127-3:2015IEC 60127-3:2015/AMD1:2020	UL/cUL （JDYX/7，E213695） VDE (40017009)
Fuse (F1, F2) (Alternate)	Interchangeable	Interchangeable	T3.15AH, 250Vac. Non-micro type	ANSI/UL 248-1/Ed.4 CSA-C22.2 No. 248-1-00	UL JDYX/7 --
Varistor (MOV1) (optional)	XIAMEN SET ELECTRONICS CO LTD	TFV8S471K TFV10S471K	Rated300Vac. 105 deg C.	ANSI/UL 1449/Ed.5 CSA-C22.2 No. 269 IEC 61051-2-2:1991 EN IEC 61051-2:2021 EN IEC 61051-1:2018	UL/cUL (VZCA2/8, E322662) TUV(J 50554061) TUV(J 50554091)
Varistor (MOV1) (optional) (Alternate)	SHANTOU HIGH-NEW TECHNOLOGY DEVELOPMNT ZONE SONGTIAN ENTERPRISE CO LTD	10D621K 14D621K	Rated 385Vac. 125 deg C	ANSI/UL 1449/Ed.5 CSA-C22.2 No. 269 IEC 61051-1:2007IEC 61051-2:1991IEC 61051-2-2:1991IEC 61051-2:1991/AMD1:2009	UL/cUL (VZCA2/8, E330837) VDE(40023049)
Varistor (MOV1)	THINKING ELECTRONIC	TVR10621	Rated 395Vac. 105	ANSI/UL 1449/Ed.5	UL/cUL (VZCA2/8,

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8.10	**TABLE:** List of critical components				Pass
Object/ Part No.	Manufacturer/ Trademark	Type / model	Technical data	Standard [2]	Mark(s) of conformity [1]
(optional) (Alternate)	INDUSTRIAL CO LTD	TVR14621	deg C	CSA-C22.2 No. 269 DIN EN IEC 61051-1:2019-07; EN IEC 61051-1:2018DIN EN IEC 61051-2:2023-10; EN IEC 61051-2:2021 IEC 61051-2-2:1991IEC 61051-1:2018IEC 61051-2:2021	E314979) VDE(005944)
Varistor (MOV1) (optional) (Alternate)	Guangdong Huiwan Electronics Technology Co Ltd	V-621K-10D H V-621K-14D H	Rated 385Vac. 125 deg C	ANSI/UL 1449/Ed.5 CSA-C22.2 No. 269 IEC 61051-2:1991IEC 61051-2-2:1991IEC 61051-1:2007IEC 61051-2:1991/AMD1:2009	UL/cUL (VZCA2/8, E480104) VDE(40043880)
Varistor (MOV1) (optional) (Alternate)	Interchangeable	Interchangeable	Rated 385Vac. 125 deg C	ANSI/UL 1449/Ed.5 CSA-C22.2 No. 269 IEC 61051-2:1991IEC 61051-2-2:1991IEC 61051-1:2007IEC 61051-2:1991/AMD1:2009	UL/cUL (VZCA2/8) VDE)
Bleeder Resistors (R10, R11)	Interchangeable	Interchangeable	Max. 100KΩ	--	-- --
Diode (D2, D3)	Interchangeable	Interchangeable	Min.1000V Min.1A	--	-- --
ICX(U1)	NXP Semiconductor Taiwan Ltd	TEA18362T	Vcc: Min 30V	IEC 62368-1:2018	TUV(JPTUV-135830)
X-Capacitor (CX1) (Optional)	CHENG TUNG INDUSTRIAL CO LTD	CTX	Rated Max.0.47µ F, Min 250Vac, 105 degC, marked X1 or X2	ANSI/UL 60384-14/Ed.2 CAN/CSA-E60384-14 (2014) EN 60384-14:2013; EN 60384-14:2013/A1:2016	UL/cUL (FOWX2/8, E193049) ENEC (ENEC-02738)
X-Capacitor (CX1) (Optional) (Alternate)	ULTRA TECH XIPHI ENTERPRISE CO LTD	HQX	Rated Max.0.47µ F, Min 250Vac, 110degC, marked X2	ANSI/UL 60384-14/Ed.2 CAN/CSA-E60384-14 (2014) DIN EN 60384-14 (VDE 0565-1-1):2014-04; EN 60384-14:2013-08DIN EN 60384-14/A1 (VDE 0565-1-1/A1):2017-04; EN 60384-14:2013/A1:2016IEC 60384-14:2013IEC 60384-14:2013/AMD1:2016	UL/cUL (FOWX2/8, E183780) VDE (40024534)
X-Capacitor (CX1) (Optional) (Alternate)	DAIN ELECTRONICS CO LTD	MEX, MPX, NPX	Rated Max.0.47µ F, Min 250Vac, 110degC, marked X1	ANSI/UL 60384-14/Ed.2 CAN/CSA-E60384-14 (2014) DIN EN 60384-14 (VDE 0565-1-1):2014-04; EN 60384-14:2013-08DIN EN 60384-14/A1 (VDE 0565-1-1/A1):2017-04;	UL/cUL (FOWX2/8, E147776) VDE (40018798)

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Clause	Requirement + Test	Result - Remark	Verdict

8.10	**TABLE:** List of critical components				Pass
Object/ Part No.	Manufacturer/ Trademark	Type / model	Technical data	Standard [2]	Mark(s) of conformity [1]
				EN 60384-14:2013/A1:2016IEC 60384-14:2013IEC 60384-14:2013/AMD1:2016	
X-Capacitor (CX1) (Optional) (Alternate)	SINHUA ELECTRONICS (HUZHOU) CO LTD	MPX	Rated Max.0.47µ F, Min 250Vac, 110 degC, markedX2	ANSI/UL 60384-14/Ed.2 CAN/CSA-E60384-14 (2014) DIN EN 60384-14 (VDE 0565-1-1):2014-04; EN 60384-14:2013-08DIN EN 60384-14/A1 (VDE 0565-1-1/A1):2017-04; EN 60384-14:2013/A1:2016IEC 60384-14:2013/AMD1:2016IE C 60384-14:2013	UL/cUL (FOWX2/8, E237560) VDE (40014686)
X-Capacitor (CX1) (Optional) (Alternate)	Shantou High-new Technology Development Zone Songtian Enterprise Co.,Ltd	MPX	Rated Max.0.47µ F, Min 275Vac, 110degC, marked X2	ANSI/UL 60384-14/Ed.2 CAN/CSA-E60384-14 (2014) DIN EN 60384-14 (VDE 0565-1-1):2014-04; EN 60384-14:2013-08DIN EN 60384-14/A1 (VDE 0565-1-1/A1):2017-04; EN 60384-14:2013/A1:2016 IEC 60384-14:2013IEC 60384-14:2013/AMD1:2016	UL/cUL (FOWX2/8, E208107) VDE (40034679)
X-Capacitor (CX1) (Optional) (Alternate)	Interchangeable	Interchangeable	Rated Max.0.47µ F, Min 250Vac, marked X1 or X2	ANSI/UL 60384-14/Ed.2 CAN/CSA-E60384-14 (2014) DIN EN 60384-14 (VDE 0565-1-1):2014-04; EN 60384-14:2013-08DIN EN 60384-14/A1 (VDE 0565-1-1/A1):2017-04; EN 60384-14:2013/A1:2016 IEC 60384-14:2013IEC 60384-14:2013/AMD1:2016	UL/cUL, FOWX2/8 VDE
Bridge Y-Capacitors (CY1, CY2) (except for F3 INSULATION DIAGRAM) – (Optional)	SUCCESS ELECTRONICS CO LTD	SE, SB	Rated max.2200pF Min 250V, 125degC, marked with Y1	ANSI/UL 60384-14/Ed.2 CAN/CSA-E60384-14 (2014) DIN EN 60384-14 (VDE 0565-1-1):2014-04; EN 60384-14:2013-08DIN EN 60384-14/A1 (VDE 0565-1-1/A1):2017-04; EN 60384-14:2013/A1:2016IEC 60384-14:2013IEC 60384-14:2013/AMD1:2016	UL/cUL (FOWX2/8, E114280) VDE(40020002) VDE(40020001)
Y-Capacitors (CY1,	TDK CORP	CD	Rated max.2200pF.	ANSI/UL 60384-14/Ed.2	UL/cUL (FOWX2/8,

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Clause	Requirement + Test	Result - Remark	Verdict

8.10	**TABLE:** List of critical components				Pass
Object/ Part No.	Manufacturer/ Trademark	Type / model	Technical data	Standard [2]	Mark(s) of conformity [1]
CY2) (except for F3 INSULATION DIAGRAM) – (Optional) (Alternate)			Min 250V, 125degC, marked with Y1 or Y2	CAN/CSA-E60384-14 (2014) DIN EN 60384-14 (VDE 0565-1-1):2014-04; EN 60384-14:2013-08DIN EN 60384-14/A1 (VDE 0565-1-1/A1):2017-04; EN 60384-14:2013/A1:2016IEC 60384-14:2013IEC 60384-14:2013/AMD1:2016	E37861) VDE (40029780)
Bridge Y-Capacitors (CY1, CY2) (except for F3 INSULATION DIAGRAM) – (Optional) (Alternate)	Shantou High-new Technology Development Zone Songtian Enterprise Co.,Ltd	CD	Rated max.2200pF. Min 250V, 125degC, marked with Y1	ANSI/UL 60384-14/Ed.2 CAN/CSA-E60384-14 (2014) DIN EN 60384-14 (VDE 0565-1-1):2014-04; EN 60384-14:2013-08DIN EN 60384-14/A1 (VDE 0565-1-1/A1):2017-04; EN 60384-14:2013/A1:2016 IEC 60384-14:2013IEC 60384-14:2013/AMD1:2016	UL/cUL (FOWX2/8, E208107) VDE (40025754)
Bridge Y-Capacitors (CY1, CY2) (except for F3 INSULATION DIAGRAM) – (Optional) (Alternate)	Guangdong Huiwan Electronics Technology Co.,LTD	AR	Rated max.2200pF 500V, 125degC, marked with Y1	ANSI/UL 60384-14/Ed.2 CAN/CSA-E60384-14 (2014) DIN EN 60384-14 (VDE 0565-1-1):2014-04; EN 60384-14:2013-08IEC 60384-14:2013IEC 60384-14:2013/AMD1:2016DIN EN 60384-14/A1 (VDE 0565-1-1/A1):2017-04; EN 60384-14:2013/A1:2016	UL/cUL (FOWX2/8, E480105) VDE (40043989)
Bridge Y-Capacitors (CY1, CY2) (except for F3 INSULATION DIAGRAM) – (Optional) (Alternate)	HAOHUA ELECTRONIC CO	CT7	Rated max.2200pF Min 250V, 125degC, marked with Y1	ANSI/UL 60384-14/Ed.2 CAN/CSA-E60384-14 (2014) DIN EN 60384-14 (VDE 0565-1-1):2014-04; EN 60384-14:2013-08DIN EN 60384-14/A1 (VDE 0565-1-1/A1):2017-04; EN 60384-14:2013/A1:2016 IEC 60384-14:2013IEC 60384-14:2013/AMD1:2016	UL/cUL (FOWX2/8, E233106) VDE (40003902)
Bridge Y-Capacitors (CY1, CY2) (except for F3 INSULATION DIAGRAM) – (Optional) (Alternate)	Interchangeable	Interchangeable	Rated max.2200pF Min 250V, marked with Y1	--	-- --

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Clause	Requirement + Test	Result - Remark	Verdict

8.10	**TABLE:** List of critical components				Pass
Object/ Part No.	Manufacturer/ Trademark	Type / model	Technical data	Standard [2]	Mark(s) of conformity [1]
Bridge Y-Capacitors (CY1, CY2) (F3 INSULATION DIAGRAM) – (Optional)	SUCCESS ELECTRONICS CO LTD	SE, SB	Rated max.1500pF Min 250V, 125degC, marked with Y1	ANSI/UL 60384-14/Ed.2 CAN/CSA-E60384-14 (2014) DIN EN 60384-14 (VDE 0565-1-1):2014-04; EN 60384-14:2013-08DIN EN 60384-14/A1 (VDE 0565-1-1/A1):2017-04; EN 60384-14:2013/A1:2016IEC 60384-14:2013IEC 60384-14:2013/AMD1:2016	UL/cUL (FOWX2/8, E114280) VDE(40020002) VDE(40020001)
Y-Capacitors (CY1, CY2) (F3 INSULATION DIAGRAM) – (Optional) (Alternate)	TDK CORP	CD	Rated max.1500pF Min 250V, 125degC, marked with Y1	ANSI/UL 60384-14/Ed.2 CAN/CSA-E60384-14 (2014) DIN EN 60384-14 (VDE 0565-1-1):2014-04; EN 60384-14:2013-08DIN EN 60384-14/A1 (VDE 0565-1-1/A1):2017-04; EN 60384-14:2013/A1:2016IEC 60384-14:2013IEC 60384-14:2013/AMD1:2016	UL/cUL (FOWX2/8, E37861) VDE (40029780)
Bridge Y-Capacitors (CY1, CY2) (F3 INSULATION DIAGRAM) – (Optional) (Alternate)	Shantou High-new Technology Development Zone Songtian Enterprise Co.,Ltd	CD	Rated max.1500pF Min 250V, 125degC, marked with Y1	ANSI/UL 60384-14/Ed.2 CAN/CSA-E60384-14 (2014) DIN EN 60384-14 (VDE 0565-1-1):2014-04; EN 60384-14:2013-08DIN EN 60384-14/A1 (VDE 0565-1-1/A1):2017-04; EN 60384-14:2013/A1:2016 IEC 60384-14:2013IEC 60384-14:2013/AMD1:2016	UL/cUL (FOWX2/8, E208107) VDE (40025754)
Bridge Y-Capacitors (CY1, CY2) (F3 INSULATION DIAGRAM) – (Optional) (Alternate)	Guangdong Huiwan Electronics Technology Co.,LTD	AR	Rated max.1500pF Min 250V, 125degC, marked with Y1	ANSI/UL 60384-14/Ed.2 CAN/CSA-E60384-14 (2014) DIN EN 60384-14 (VDE 0565-1-1):2014-04; EN 60384-14:2013-08IEC 60384-14:2013IEC 60384-14:2013/AMD1:2016DIN EN 60384-14/A1 (VDE 0565-1-1/A1):2017-04; EN 60384-14:2013/A1:2016	UL/cUL (FOWX2/8, E480105) VDE (40043989)
Bridge Y-Capacitors (CY1, CY2) (F3 INSULATION DIAGRAM) – (Optional)	HAOHUA ELECTRONIC CO	CT7	Rated max.1500pF Min 250V, 125degC, marked with Y1	ANSI/UL 60384-14/Ed.2 CAN/CSA-E60384-14 (2014) DIN EN 60384-14 (VDE 0565-1-1):2014-04; EN 60384-14:2013-08DIN	UL/cUL (FOWX2/8, E233106) VDE (40003902)

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Clause	Requirement + Test	Result - Remark	Verdict

8.10	**TABLE:** List of critical components				Pass
Object/ Part No.	Manufacturer/ Trademark	Type / model	Technical data	Standard [2]	Mark(s) of conformity [1]
(Alternate)				EN 60384-14/A1 (VDE 0565-1-1/A1):2017-04; EN 60384-14:2013/A1:2016 IEC 60384-14:2013IEC 60384-14:2013/AMD1:2016	
Bridge Y-Capacitors (CY1, CY2) (F3 INSULATION DIAGRAM) – (Optional) (Alternate)	Interchangeable	Interchangeable	Rated max.1500pF Min 250V, 125degC, marked with Y1	--	--
Capacitors (CY3) - (Optional， only for F3 insulation construction)	Interchangeable	Interchangeable	Rated Max.10μ F, Min. 50V	--	-- --
Resistors (R20) - (Optional， only for F2 insulation construction)	Interchangeable	Interchangeable	Rated Max. 10KΩ		
Line Filter (LF2) (optional)	GLOBTEK/HAOPUWEI	NF00031	130 degree C, min.10mH	--	--
Line Filter (LF2) (optional) (Alternate)	Interchangeable	Interchangeable	130 degree C, min.10mH	--	--
Line Filter (LF1) (optional)	GLOBTEK/HEJIA	GTM91099-LF1	Min.200uH		
Line Filter (LF1) (optional) (Alternate)	Interchangeable	Interchangeable	min.200uH		
BD1	Interchangeable	Interchangeable	Min. 4A, Min. 600V	--	-- --
Transistor (Q1)	Interchangeable	Interchangeable	Rated min 7A, Min. 600V	--	--
Transformer (T1) (Alternate)	GLOBTEK INC / WUXI HAOPUWEI ELECTRONICS CO LTD	TF058, TF059, TF063, TF060, TF064, TF061	Class B. See enclosure Diagrams-(004) to (008) for construction details.	--	--
- Insulation system used in T1	GLOBTEK INC	GTX-130-TM	Class 130 (B) Insulation System.	ANSI/UL 1446/Ed.8	UL (OBJY2, E243347)
- Insulation system used in T1 (Alternate)	WUXI HAOPUWEI ELECTRONICS CO LTD	ZT-130	Class 130 (B) Insulation System.	ANSI/UL 1446/Ed.8	UL (OBJY2, E315275)
- Primary winding used in T1	Interchangeable	Interchangeable	Min.130 degC		--
- Secondary winding used in T1	HOI LUEN ELECTRICAL MFR CO LTD	THL-F-xx	Rated 130 degC Triple insulated wire	ANSI/UL 2353/Ed.3 DIN EN IEC 62368-1 (VDE 0868-1):2021-05; EN IEC 62368-1:2020+A11:2020IEC 62368-1:2018	UL (OBJT2, E257525) VDE(40020365)

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Clause	Requirement + Test	Result - Remark	Verdict

8.10	**TABLE:** List of critical components				Pass
Object/ Part No.	Manufacturer/ Trademark	Type / model	Technical data	Standard [2]	Mark(s) of conformity [1]
- Secondary winding used in T1(Alternate)	GREAT LEOFLON INDUSTRIAL CO LTD	TRW(B)	Rated 130 degC Triple insulated wire	ANSI/UL 2353/Ed.3 DIN EN 62368-1 (VDE 0868-1):2016-05; EN 62368-1:2014DIN EN 62368-1/A11 (VDE 0868-1/A11):2017-11; EN 62368-1:2014/A11:2017DIN EN IEC 62368-1 (VDE 0868-1):2021-05; EN IEC 62368-1:2020+A11:2020 IEC 62368-1:2014IEC 62368-1:2018	UL (OBJT2, E211989) VDE (136581)
- Bobbin used in T1	CHANG CHUN PLASTICS CO LTD	T375J, T375HF	Phenolic, rated V-0, 150 degC,	ANSI /UL 746B/Ed.5	UL (QMFZ2, E59481) --
- Bobbin used in T1 (Alternate)	SUMITOMO	PM-9820,PM-9830PM-9823,PM-9630	Phenolic, rated V-0, 150 degC,	ANSI /UL 746B/Ed.5	UL (QMFZ2, E41429) --
- Bobbin used in T1 (Alternate)	CHANG CHUN PLASTICS CO LTD	4130	Phenolic, rated V-0, 150 degC,	ANSI /UL 746B/Ed.5	UL (QMFZ2, E59481) --
- Insulation Tape used in T1	JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CO LTD	PZ, CT, WF	Rated 130 degC.	CAN/UL 510A/Ed.2	UL (OANZ2, E165111)
- Insulation Tape used in T1 (Alternate)	JINGJIANG JINGYI ADHESIVE PRODUCT CO LTD	JY25-A	Rated 130 degC.	CAN/UL 510A/Ed.2	UL (OANZ2, E246950)
- Insulation Tape used in T1 (Alternate)	BONDTEC PACIFIC CO LTD	370S	Rated 130 degC.	CAN/UL 510A/Ed.2	UL (OANZ2, E175868)
- Insulation Tape used in T1 (Alternate)	CHANG SHU LIANG YI TAPE INDUSTRY CO LTD	LY-XX*	Rated 130 degC.	CAN/UL 510A/Ed.2	UL (OANZ2, E246820)
- Insulation Tape used in T1 (Alternate)	3M COMPANY	1350T-1, 1350F(#), 44	Rated 130 degC.	CAN/UL 510A/Ed.2	UL (OANZ2, E17385)
- Varnish used in T1	SUZHOU TAIHU ELECTRIC ADVANCED MATERIAL CO LTD	T-4260(a)	Rated 130 degC.	ANSI/UL 1446/Ed.8	UL (OBOR2, E228349)
- Tube	GREAT HOLDING INDUSTRIAL CO LTD	TFL, TFT	VW-1. Rated 150V, 200 degC for TFL; Rated 300V, 200 degC for TFT	ANSI/UL 224/Ed.7	UL (YDPU2, E156256)
- Tube (Alternate)	SHENZHEN WOER HEAT-SHRINKABLE MATERIAL CO LTD	WF	VW-1. Rated 600V, 200 degC	ANSI/UL 224/Ed.7	UL (YDPU2, E203950)
- Tube (Alternate)	CHANGYUAN ELECTRONICS GROUP CO LTD	CB-TT-T, CB-TT-S	VW-1. Rated min.300V, 200 degC	ANSI/UL 224/Ed.7	UL (YDPU2, E180908)
Opto-couplers (U4)	EVERLIGHT ELECTRONICS CO LTD	EL817	Rated min. 110degC Provide min 5000Vac isolation test voltage rating. Ext. Dcr&Cl: ≥8.0mm,	ANSI/UL 1577/Ed.5 CAN/CSA Component Acceptance Service Notice No. 5A DIN EN IEC 60747-5-5	UL/cUL (FPQU2/8, E214129) VDE (132249)

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8.10	**TABLE:** List of critical components				Pass
Object/ Part No.	Manufacturer/ Trademark	Type / model	Technical data	Standard [2]	Mark(s) of conformity [1]
			DTI: ≥0.4mm,	(VDE 0884-5):2021-10; EN IEC 60747-5-5:2020 IEC 60747-5-5:2020	
Opto-couplers (U4) (Alternate)	LITE-ON TECHNOLOGY CORP	LTV-817M, LTV-817, LTV-817S	Rated min. 115degC Provide min 5000Vac isolation test voltage rating. Ext. Dcr&Cl: ≥8.0mm, DTI: ≥0.4mm	ANSI/UL 1577/Ed.5 CAN/CSA Component Acceptance Service Notice No. 5A DIN EN IEC 60747-5-5 (VDE 0884-5):2021-10; EN IEC 60747-5-5:2020 IEC 60747-5-5:2020	UL/cUL (FPQU2/8, E113898) VDE (40015248)
Opto-couplers (U4) (Alternate)	Bright Led Electronics Corp.	BPC-817M	Rated min. 100degC Provide min 5000Vac isolation test voltage rating. Ext. Dcr&Cl: ≥8.0mm, DTI: ≥0.4mm	ANSI/UL 1577/Ed.5 CAN/CSA Component Acceptance Service Notice No. 5A DIN EN IEC 60747-5-5 (VDE 0884-5):2021-10; EN IEC 60747-5-5:2020 IEC 60747-5-5:2020	UL/cUL (FPQU2/8, E236324) VDE (40007240)
Heat Sink - HS1	--	--	Aluminium. Approximate overall dimension (42.9mm+23.5mm） *82mm, 2.0mm thick, secured to PWB by soldering.	--	--
Heat Sink - HS2	--	--	Aluminium. Approximate overall dimension （103.5+14.5）x 24.3mm or （78.1+14.5）x 24.3mm, 2.0mm thick, secured to PWB by soldering.	--	--
Heat shrink Tube on HS2	Interchangeable	Interchangeable	Rated 130 degree C, min 0.4 mm thickness	UL 224	UL YDPU2
Insulation tape provided on HS1	3M COMPANY ELECTRICAL MARKETS DIV (EMD)	1350F-1, 1350T-1	Rated 130 degC, 117mm by 40mm, 1layers (0.05 mm) 87mm by 25mm, 2layers (0.025*2 mm) 101mm by 20mm, 2layers (0.025*2 mm). See enclosure diagram – (009) for details.	CAN/UL 510A/Ed.2	UL (OANZ2, E17385)
Insulation tape provided on HS1 (Alternate)	JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CO LTD	PZ, CT	Rated 130 degC. 117mm by 40mm, 1layers (0.05 mm) 87mm by 25mm, 2layers (0.025*2 mm) 101mm by 20mm, 2layers (0.025*2 mm)	CAN/UL 510A/Ed.2	UL (OANZ2, E165111)
Insulation tape provided on HS1	JINGJIANG JINGYI ADHESIVE PRODUCT CO	JY25-A	Rated 130 degC. 117mm by 40mm,	CAN/UL 510A/Ed.2	UL (OANZ2, E246950)

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8.10	**TABLE:** List of critical components				Pass
Object/ Part No.	Manufacturer/ Trademark	Type / model	Technical data	Standard [2]	Mark(s) of conformity [1]
(Alternate)	LTD		1layers (0.05 mm) 87mm by 25mm, 2layers (0.025*2 mm) 101mm by 20mm, 2layers (0.025*2 mm)		
Insulation tape provided on HS1(Alternate)	BONDTEC PACIFIC CO LTD	370S	Rated 130 degC. 117mm by 40mm, 1layers (0.05 mm) 87mm by 25mm, 2layers (0.025*2 mm) 101mm by 20mm, 2layers (0.025*2 mm)	CAN/UL 510A/Ed.2	UL (OANZ2, E175868)
Insulation tape provided on HS1 (Alternate)	CHANG SHU LIANG YI TAPE INDUSTRY CO LTD	LY-XX*	Rated 130 degC. 117mm by 40mm, 1layers (0.05 mm) 87mm by 25mm, 2layers (0.025*2 mm) 101mm by 20mm, 2layers (0.025*2 mm)	CAN/UL 510A/Ed.2	UL (OANZ2, E246820)
Output cord	Interchangeable	Interchangeable	Min. 24AWG, min. VW-1, min. 80°C, min. 300V.	UL 758: 3rd edition	UL(AVLV2, ZJCZ)
Primary Cord guard (for desktop model) (Optional)	Interchangeable	Interchangeable	Min. V-2. Dimension about 30.8 by 24mm. See enclosure diagram – (013) for details	UL 94	UL QMFZ2
Primary Cord guard (For Encapsulated model)	Interchangeable	Interchangeable	Min. V-2. Dimension about 14.6 by 8.4mm. See enclosure diagram – (014) for details	UL 94	UL QMFZ2
Secondary cord guard (for desktop model)	Interchangeable	Interchangeable	Min. V-2. Dimension about 9.4 by 7.4mm	UL 94	UL QMFZ2
Secondary cord guard (for hybrid desktop model)	Interchangeable	Interchangeable	Min. V-2. Dimension about 9 by 6.7mm	UL 94	UL QMFZ2
Secondary cord guard (for Encapsulated model)	Interchangeable	Interchangeable	Min. V-2. Dimension about 14.6 by 8.4mm.	UL 94	UL QMFZ2
Label (Provided if not using engraving or silkscreen or Laser printing)	DONGGUAN XIANGQUAN PRINTING CO LTD	XQ03	Rated min 80 degC C. Suitable for use on the plastic enclosure.	ANSI/UL 969/Ed.5	UL (PGDQ2, MH27594)
Label (Provided if not using engraving or silkscreen or Laser printing) (Alternate)	FAN JA PAPER PRINTING CO LTD	FJ-03-3, FJ-03-1	Rated min 80 degC C. Suitable for use on the plastic enclosure.	ANSI/UL 969/Ed.5	UL (PGDQ2, MH19546)
Label (Provided if	FAN JA PAPER PRINTING	FJ07, FJ10	Rated min 80 degC C.	ANSI/UL 969/Ed.5	UL (PGDQ2, MH19546)

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8.10	**TABLE:** List of critical components				Pass
Object/ Part No.	Manufacturer/ Trademark	Type / model	Technical data	Standard [2]	Mark(s) of conformity [1]
not using engraving or silkscreen or Laser printing) (Alternate)	CO LTD		Suitable for use on the plastic enclosure.		
Label (Provided if not using engraving or silkscreen or Laser printing) (Alternate)	DONGGUAN XIANGQUAN PRINTING CO LTD	XQ004-B	Rated min 80 degC C. Suitable for use on the plastic enclosure.	ANSI/UL 969/Ed.5	UL (PGJI2, MH47303)
Label (Provided if not using engraving or silkscreen or Laser printing) (Alternate)	E-LIN ADHESIVE LABEL CO LTD	EL-15	Rated min 80 degC C. Suitable for use on the plastic enclosure.	ANSI/UL 969/Ed.5	UL (PGDQ2, MH45549)
Label (Provided if not using engraving or silkscreen or Laser printing) (Alternate)	SHENZHEN CORWIN PRINTING CO LTD	CW-01	Rated min 80 degC C. Suitable for use on the plastic enclosure.	ANSI/UL 969/Ed.5	UL (PGDQ2, MH47077)
Label (Provided if not using engraving or silkscreen or Laser printing) (Alternate)	YUEN CHANG SPECIAL PRINTING (SHENZHEN) CO LTD	JL-08, JL-02	Rated min 80 degC C. Suitable for use on the plastic enclosure.	ANSI/UL 969/Ed.5	UL (PGDQ2, MH29752)
Label (Provided if not using engraving or silkscreen or Laser printing) (Alternate)	SUZHOU HAIRONG PACKING PRODUCTION CO LTD	HR-01 HR-04 HR-05	Rated min 80 deg C Suitable for use on the plastic enclosure	ANSI/UL 969/Ed.5	UL (PGDQ2, MH48692)
Label (Provided if not using engraving or silkscreen or Laser printing) (Alternate)	DONGGUAN SHANGMAO PRINTING CO LTD	C-019, C-004	Rated min 80 deg C Suitable for use on the plastic enclosure	ANSI/UL 969/Ed.5	UL (PGDQ2, MH17427)
Label (Provided if not using engraving or silkscreen or Laser printing) (Alternate)	ZHONGSHAN ZHANTU P RINTING CO LTD	ZT969-1ZT969-2ZT969-3	Rated min 80 deg C Suitable for use on the plastic enclosure	ANSI/UL 969/Ed.5	UL (PGDQ2, MH47528)
PWB	Interchangeable	Interchangeable	Min. V-1, 130°C	UL 796	UL (ZPMV2)
Encapsulation (For Encapsulation construction only)	Dong Guan Shi Pai Hua Chuang Material FTY	808A/B	Rated V-0, 90 degC. heat conductivity: 0.3 W/mK.	ANSI /UL 746B/Ed.5	UL (QMFZ2, E304477)
Encapsulation (For Encapsulation construction only) - Alternate	SUZHOU POCHELY ELECTRONIC MATERIAL CO LTD	HB-5225A/B	Rated V-0, minimum 90 Deg C. heat conductivity: 0.3 W/mK.	ANSI /UL 746B/Ed.5	UL (QMFZ2, E304947)
Encapsulation (For Encapsulation construction only) - Alternate	DONGGUAN EATTO ELECTRONIC MATERIAL CO LTD	3300A/B	Rated V-0, minimum 90 Deg C. heat conductivity: 1.45 x 10-3s/cm/°C	ANSI /UL 746B/Ed.5	UL (QMFZ2, E218090)
Encapsulation (For Encapsulation	GUANGZHOU BAIYUN CHEMICAL INDUSTRY	SLF385A/SLF385B	Rated V-0, minimum 105 Deg C.	ANSI /UL 746B/Ed.5	UL (QMFZ2, E252101)

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8.10	**TABLE:** List of critical components				Pass
Object/ Part No.	Manufacturer/ Trademark	Type / model	Technical data	Standard [2]	Mark(s) of conformity [1]
construction only) - Alternate	CO LTD		conductivity: 0.68W/mK.		
Encapsulation (For Encapsulation construction only) - Alternate	SUZHOU DATONG ADVANCED MATERIAL CO LTD	TT 700	Rated V-0, minimum 105 Deg C. conductivity: 0.8W/mK.	ANSI /UL 746B/Ed.5	UL (QMFZ2, E341902)
AC Power Plug of Power cord (For TP EU standard)	YUNG- LI COLTD	YP-21A	250V, 2.5A	DIN VDE 0620 Teil 101:1992-05; EN 50075:1990	VDE (40022312)
- Alternate	Self-Man Industrial Co., Ltd.	SH-037	250V, 2.5A	DIN VDE 0620 Teil 101:1992-05; EN 50075:1990	VDE (101016)
-Flexible cable of power cord (optional) (For P2, TP, TW EU standard)	Yung-Li Co. Ltd..	H03VVH2-F	2X0.75mm2	DIN EN 50525-2-11 (VDE 0285-525-2-11):2012-01; EN 50525-2-11:2011	VDE (40010145)
- Alternate	I-Sheng ElectricWire & Cable	H03VVH2-F	2X0.75mm2	DIN EN 50525-2-11 (VDE 0285-525-2-11):2012-01; EN 50525-2-11:2011	VDE (40015762)
- Alternate	Suzhou Tongyuan Electric	H03VVH2-F	2X0.75mm2	DIN EN 50525-2-11 (VDE 0285-525-2-11):2012-01; EN 50525-2-11:2011	VDE (128253)
- Alternate	Interchangeable	Interchangeable		DIN EN 50525-2-11 (VDE 0285-525-2-11):2012-01; EN 50525-2-11:2011	VDE (128253)
AC Power Plug of Power cord (For, TP3 EU standard)	Self-Man Industrial Co., Ltd.	SH-025	250V, 16A	DIN VDE 0620-2-1 (VDE 0620-2-1):2016-01DIN VDE 0620-2-1/A1 (VDE 0620-2-1/A1):2017-09 DIN VDE 0620-2-1/A1 (VDE 0620-2-1/A1):2023-09	VDE (40008942)
-Flexible cable of power cord (For TP3 TW3 EU standard)	I-Sheng ElectricWire & Cable	H05VV-F	3X0.75mm2	DIN EN 50525-2-11 (VDE 0285-525-2-11):2012-01; EN 50525-2-11:2011	VDE (40015762)
- Alternate	Yung-Li Co. Ltd..	H05VV-F	3X0.75mm2	DIN EN 50525-2-11 (VDE 0285-525-2-11):2012-01; EN 50525-2-11:2011	VDE (40010145)
- Alternate	Suzhou Tongyuan Electric	H05VV-F	3X0.75mm2	DIN EN 50525-2-11 (VDE 0285-525-2-11):2012-01; EN 50525-2-11:2011	VDE (128253)
- Alternate	Interchangeable	Interchangeable	3X0.75mm2	--	-- VDE
AC Power Plug of Power cord(For TP, NA standard)	Self-Man Industrial Co., Ltd.	SM-045	125V, 10A	ANSI/UL 817/Ed.12 CSA C22.2 No. 21	UL/cUL (ELBZ/7, E119543)

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.10	**TABLE:** List of critical components				Pass
Object/ Part No.	Manufacturer/ Trademark	Type / model	Technical data	Standard [2]	Mark(s) of conformity [1]
- Alternate	YUNG LI CO LTD	YC-12	125V, 10A	ANSI/UL 817/Ed.12 CSA C22.2 No. 21	UL/cUL (ELBZ/7, ELBZ2/8, E152635)
- Alternate	JHI WEIELECTRIC WIRE& CABLE COLTD	JW-03	125V, 10A	ANSI/UL 817/Ed.12 CSA C22.2 No. 21	UL/cUL (ELBZ/7, E222747)
-Flexible cable of power cord (For, TP, TW NA standard)	I SHENGELECTRONICS(KUNSHAN) COLTD	SPT-1, SPT-2	Min.18AWG, min. 60°C,Min.300V, VW-1	ANSI/UL 62/Ed.20 CSA C22.2 No. 49	UL/cUL (ZJCZ/7, E314513)
- Alternate	YUNG LI CO LTD	SPT-1, SPT-2	Min.18AWG, min. 60°C	ANSI/UL 62/Ed.20 CSA C22.2 No. 49	UL/cUL (ZJCZ/7, E241374）
- Alternate	JHI WEIELECTRIC WIRE& CABLE COLTD	SPT-1, SPT-2	Min.18AWG, min. 60°C	ANSI/UL 62/Ed.20 CSA C22.2 No. 49	UL/cUL (ZJCZ/7, E222747）
- Alternate	SUZHOUTONGYUANELECTRIC WIRE& CABLE COLTD	SPT-1, SPT-2	Min.18AWG, min. 60°C	ANSI/UL 62/Ed.20 CSA C22.2 No. 49	UL/cUL (ZJCZ/7, E230449）
- Alternate	Interchangeable	Interchangeable	Min.18AWG, min. 60°C		UL
AC Power Plug of Power cord(ForTP3, NA standard)	Self-Man Industrial Co., Ltd.	SM-001	125V, 10A	ANSI/UL 817/Ed.12 CSA C22.2 No. 21	UL/cUL (ELBZ/7, E119543)
-Flexible cable of power cord (For TP3, TW3 NA standard)	I SHENGELECTRONICS(KUNSHAN) COLTD	SVT	Min.18AWG,min. 105°CMin.300V, VW-1	ANSI/UL 62/Ed.20 CSA C22.2 No. 49	UL/cUL (ZJCZ/7, E314513)
- Alternate	YUNG LI CO LTD	SVT	Min.18AWG,min. 105°CMin.300V, VW-1	ANSI/UL 62/Ed.20 CSA C22.2 No. 49	UL/cUL (ZJCZ/7, E241374）
- Alternate	SUZHOUTONGYUANELECTRIC WIRE& CABLE COLTD	SVT	Min.18AWG,min. 105°CMin.300V, VW-1	ANSI/UL 62/Ed.20 CSA C22.2 No. 49	UL/cUL (ZJCZ/7, E230449）
- Alternate	Interchangeable	Interchangeable	Min.18AWG, min. 105°C Min.300V, VW-1		UL
AC Power Plug of Power cord (For P2 EU standard)	YUNG- LI COLTD	YP-21A	250V, 2.5A	DIN VDE 0620 Teil 101:1992-05; EN 50075:1990	VDE (40022312)
- Alternate	Self-Man Industrial Co., Ltd.	SH-037	250V, 2.5A	DIN VDE 0620 Teil 101:1992-05; EN 50075:1990	VDE(101016)
-Flexible cable of power cord (For P2, EU standard)	Yung-Li Co. Ltd..	H03VVH2-F	2X0.75mm2	DIN EN 50525-2-11 (VDE 0285-525-2-11):2012-01; EN 50525-2-11:2011	VDE (40010145)
- Alternate	I-Sheng ElectricWire & Cable	H03VVH2-F	2X0.75mm2	DIN EN 50525-2-11 (VDE 0285-525-2-11):2012-01; EN 50525-2-11:2011	VDE (40015762)

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.10	**TABLE:** List of critical components				Pass
Object/ Part No.	Manufacturer/ Trademark	Type / model	Technical data	Standard [2]	Mark(s) of conformity [1]
- Alternate	Suzhou Tongyuan Electric	H03VVH2-F	2X0.75mm2	DIN EN 50525-2-11 (VDE 0285-525-2-11):2012-01; EN 50525-2-11:2011	VDE(128253)
- Alternate	Interchangeable	Interchangeable	2X0.75mm2	--	-- VDE
AC Power Plug of Power cord (For P3 EU standard)	Self-Man Industrial Co., Ltd.	SH-025	250V, 16A	DIN VDE 0620-2-1 (VDE 0620-2-1):2016-01DIN VDE 0620-2-1/A1 (VDE 0620-2-1/A1):2017-09 DIN VDE 0620-2-1/A1 (VDE 0620-2-1/A1):2023-09	VDE (40008942)
-Flexible cable of power cord (For P3 EU standard)	I-Sheng ElectricWire & Cable	H05VV-F	3X0.75mm2	DIN EN 50525-2-11 (VDE 0285-525-2-11):2012-01; EN 50525-2-11:2011	VDE (40015762)
- Alternate	Yung-Li Co. Ltd..	H05VV-F	3X0.75mm2	DIN EN 50525-2-11 (VDE 0285-525-2-11):2012-01; EN 50525-2-11:2011	VDE (40010145)
- Alternate	Suzhou Tongyuan Electric	H05VV-F	3X0.75mm2	DIN EN 50525-2-11 (VDE 0285-525-2-11):2012-01; EN 50525-2-11:2011	VDE(128253)
- Alternate	Interchangeable	Interchangeable	3X0.75mm2	--	-- VDE
AC Power Plug of Power cord (For P2 NA standard)	Self-Man Industrial Co., Ltd.	SM-045	125V, 10A	ANSI/UL 817/Ed.12 CSA C22.2 No. 21	UL/cUL (ELBZ/7) (E119543)
- Alternate	YUNG LI CO LTD	YC-12	125V, 10A	ANSI/UL 817/Ed.12 CSA C22.2 No. 21	UL/cUL (ELBZ/7, ELBZ2/8) (E152635)
- Alternate	JHI WEIELECTRIC WIRE& CABLE COLTD	JW-03	125V, 10A	ANSI/UL 817/Ed.12 CSA C22.2 No. 21	UL/cUL (ELBZ/7)(E222747)
-Flexible cable of power cord (For P2 NA standard)	I SHENGELECTRONICS(KUNSHAN) COLTD	SPT-1, SPT-2	Min.18AWG, min. 60°C,Min.300V, VW-1	ANSI/UL 62/Ed.20 CSA C22.2 No. 49	UL/cUL (ZJCZ/7) (E314513)
- Alternate	YUNG LI CO LTD	SPT-1, SPT-2	Min.18AWG, min. 60°C	ANSI/UL 62/Ed.20 CSA C22.2 No. 49	UL/cUL (ZJCZ/7) （E241374）
- Alternate	JHI WEIELECTRIC WIRE& CABLE COLTD	SPT-1, SPT-2	Min.18AWG, min. 60°C	ANSI/UL 62/Ed.20 CSA C22.2 No. 49	UL/cUL (ZJCZ/7) （E222747）
- Alternate	SUZHOUTONGYUANELECTRIC WIRE& CABLE COLTD	SPT-1, SPT-2	Min.18AWG, min. 60°C	ANSI/UL 62/Ed.20 CSA C22.2 No. 49	UL/cUL (ZJCZ/7) （E230449）
- Alternate	Interchangeable	Interchangeable	Min.18AWG, min. 60°C		UL

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.10	**TABLE:** List of critical components				Pass
Object/ Part No.	Manufacturer/ Trademark	Type / model	Technical data	Standard [2]	Mark(s) of conformity [1]
AC Power Plug of Power cord (For P3 NA standard)	Self-Man Industrial Co., Ltd.	SM-001	125V, 10A	ANSI/UL 817/Ed.12 CSA C22.2 No. 21	UL/cUL (ELBZ/7) (E119543)
-Flexible cable of power cord (For P3 NA standard)	I SHENGELECTRONICS(KUNSHAN) COLTD	SVT	Min.18AWG,min. 105°CMin.300V, VW-1	ANSI/UL 62/Ed.20 CSA C22.2 No. 49	UL/cUL (ZJCZ/7) (E314513)
- Alternate	YUNG LI CO LTD	SVT	Min.18AWG,min. 105°CMin.300V, VW-1	ANSI/UL 62/Ed.20 CSA C22.2 No. 49	UL/cUL (ZJCZ/7) （E241374）
- Alternate	SUZHOUTONGYUANELECTRIC WIRE& CABLE COLTD	SVT	Min.18AWG,min. 105°CMin.300V, VW-1	ANSI/UL 62/Ed.20 CSA C22.2 No. 49	UL/cUL (ZJCZ/7) （E230449）
- Alternate	JIANGSU SUCCESS ELECTRONICS CO LTD	SJT	Min.18AWG,min. 105°CMin.300V, VW-1	ANSI/UL 62/Ed.20 CSA C22.2 No. 49	UL/cUL (ZJCZ/7) （E485855）
- Alternate	Interchangeable	Interchangeable	Min.18AWG, min. 105°C		UL
Connector (Alternate) insteadof AC Power Plug(For P3 series)	Wieland Electric GmbH	GST18I3 Serie	250V, 20A	DIN EN IEC 61535 (VDE 0606-200):2020-08; EN IEC 61535:2019 ANSI/UL 1944/Ed.4 CSA C22.2 No. 182.3	UL/cUL（ECBT2） （E90664） VDE (40018414)
Connector (Alternate) insteadof AC Power Plug(For P3 series	Interchangeable	Interchangeable	250V, 20A	DIN EN IEC 61535 (VDE 0606-200):2020-08; EN IEC 61535:2019 ANSI/UL 1944/Ed.4 CSA C22.2 No. 182.3	UL/cUL, ECBT2 VDE
Input Lead Wire insteadof AC Power cord(For P2, P3, TW, TW3 Series)	Interchangeable	Interchangeable	Rated min 300V,min. 80°C, min 18AWG,min.VW-1	UL 758	UL, cUL AVLV2/8
Internal wire	Interchangeable	Interchangeable	Min. 20 AWG. Min.300V Min. 80°C Min.Vw-1	UL 758	UL, cUL AVLV2/8
COPPER FOIL (Only for Desktop models)	--	--	78 by 39.8mm, 0.3mm thick	--	-- --
Insulator (Only for Desktop models)	FORMEX	FORMEX GK-(a)(d)(f2)	Provided between PWB and Enclosure. Rated V-0, 115 degC. Overall measured 107.6 by 46.80mm, 0.4mm thick.	ANSI /UL 94/Ed.7 ANSI /UL 746B/Ed.5	UL (QMFZ2, E121855)
Insulator (Only for Desktop models) (Alternate)	CHENGDU KANGLONGXIN PLASTICS CO LTD	KLX PP BK-10 series, KLX PP BK-17, KLX PP WT-10 series	Provided between PWB and Enclosure. Rated V-0, 105 degC. Overall measured 107.6 by 46.80mm, 0.4mm thick.	ANSI /UL 94/Ed.7 ANSI /UL 746B/Ed.5	UL (QMFZ2, E315185)
Insulator (Only for	Sichuan Longhua Film	PP-(i)(j)	Provided between	ANSI /UL 94/Ed.7	UL (QMFZ2, E254551)

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.10	**TABLE:** List of critical components				Pass
Object/ Part No.	Manufacturer/ Trademark	Type / model	Technical data	Standard [2]	Mark(s) of conformity [1]
Desktop models) (Alternate)	Co Ltd		PWB and Enclosure. Rated V-0, 105 degC. Overall measured 107.6 by 46.80mm, 0.4mm thick.	ANSI /UL 746B/Ed.5	
Insulator (Only for Desktop models) (Alternate)	ITW Materials Technology (Shanghai) Co.,LTD	FORMEX GK-(a)(d)(f2)	Provided between PWB and Enclosure. Rated V-0, 115 degC. Overall measured 107.6 by 46.80mm, 0.4mm thick.	ANSI /UL 94/Ed.7 ANSI /UL 746B/Ed.5	UL (QMFZ2, E256266)
Insulator (Only for Desktop models) (Alternate)	F&S China Co., Ltd.	EFR95(yy)	Provided between PWB and Enclosure. Rated V-0, 130degC. Overall measured 107.6 by 46.80mm, 0.4mm thick.	ANSI /UL 94/Ed.7 ANSI /UL 746B/Ed.5	UL (QMFZ2, E539253)
License available upon request	--	--	--	--	--

Supplementary information:

The (CB) Test Laboratory has verified the component information.

1) Provided evidence ensures the agreed level of compliance. See OD-CB2039.

2) Anything specified within brackets "( )" is for reference purposes only and can be used to specify the UL Product Category CCN(s)/File Number if the component includes an UL Certification. This can be useful for the UL Follow-Up Service Inspection associated with the UL Mark; however if in brackets, should not be a required element of the UL Inspection.

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

----------END OF MAIN REPORT----------

APPENDIX A: Enclosures

Collateral/Particular Standard Enclosures

Enclosures

Supplement ID	Description
Collateral Standard - (001)	IEC 60601-1-6L
Collateral Standard - (002)	IEC 60601-1-11G

Collateral Standard - (001) IEC 60601-1-6L

Collateral Standard - (001) IEC 60601-1-6L

Test Report issued under the responsibility of:

UL Solutions

TEST REPORT
IEC 60601-1-6
Medical electrical equipment - Part 1-6:
General requirements for basic safety and essential performance - Collateral standard: Usability

Report Number..... :	**E341350-D1012 (IEC 60601-1-6)**
Date of issue ..... :	**See IEC 60601-1 test report**
Total number of pages ..... :	**15**
Name of Testing Laboratory preparing the Report ..... :	**UL-CCIC Company Limited Guangzhou Branch**
Applicant's name..... :	**See IEC 60601-1 test report**
Address ..... :	**See IEC 60601-1 test report**
Test specification:	
Standard ..... :	IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013, IEC 60601-1-6:2010/AMD2:2020 for use in conjunction with IEC 62366-1:2015, IEC 62366-1:2015/AMD1:2020, and IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
Test procedure..... :	CB Scheme
Non-standard test method..... :	N/A
TRF template used ..... :	IECEE OD-2020-F1:2022, Ed.1.5
Test Report Form No. ..... :	IEC60601_1_6L
Test Report Form(s) Originator.... :	TÜV Rheinland LGA Products GmbH
Master TRF ..... :	Dated 2023-06-01

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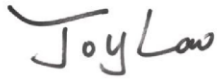
If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed.

This report is not valid as a CB Test Report unless signed by an approved IECEE Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

General disclaimer:

The test results presented in this report relate only to the object tested.
This report shall not be reproduced, except in full, without the written approval of the Issuing NCB. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.

Collateral Standard - (001) IEC 60601-1-6L

Test item description ..... :	See IEC 60601-1 test report		
Trademark(s) ..... :	See IEC 60601-1 test report		
Manufacturer ..... :	See IEC 60601-1 test report		
Model/Type reference ..... :	See IEC 60601-1 test report		
Ratings ..... :	See IEC 60601-1 test report		
Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):			
☒ **CB Testing Laboratory:**	UL-CCIC Company Limited Guangzhou Branch		
Testing location/ address.....:	Room 101 & 401, Block A, R&D Building, Room 101, 201, 301, & 401, Block B, Electronic Building, No.8, Nanyun Er Road, Huangpu District Guangzhou China		
Tested by (name, function, signature).....:	Skye Mo, Project handler		
Approved by (name, function, signature)...:	Joy Lao, Project reviewer		
☐ **Testing procedure: CTF Stage 1:**			
Testing location/ address.....:			
Tested by (name, function, signature).....:			
Approved by (name, function, signature)...:			
☐ **Testing procedure: CTF Stage 2:**			
Testing location/ address.....:			
Tested by (name + signature).....:			
Witnessed by (name, function, signature) .:			
Approved by (name, function, signature)...:			
☐ **Testing procedure: CTF Stage 3:**			
☐ **Testing procedure: CTF Stage 4:**			
Testing location/ address.....:			
Tested by (name, function, signature).....:			
Witnessed by (name, function, signature) .:			
Approved by (name, function, signature)...:			
Supervised by (name, function, signature) :			

Collateral Standard - (001) IEC 60601-1-6L

List of Attachments (including a total number of pages in each attachment): ANNEX I – IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist (Pages: 7 to 15)	
Summary of testing:	
Tests performed (name of test, test clause and date test performed): Process standard only, no testing	**Testing location: (CBTL, SPTL, CTF, Subcontractor)** N/A
Summary of compliance with National Differences (List of countries addressed): None ☐ ~~**The product fulfils the requirements of _____ (insert standard number and Year of publication, and delete the text in parenthesis, leave it blank or delete the whole sentence, if not applicable)**~~	
Use of uncertainty of measurement for decisions on conformity (decision rule) : ☒ No decision rule is specified by the IEC standard, when comparing the measurement result with the applicable limit according to the specification in that standard. The decisions on conformity are made without applying the measurement uncertainty ("simple acceptance" decision rule, previously known as "accuracy method"). ☐ Other: … (to be specified, for example when required by the standard or client, or if national accreditation requirements apply) **Information on uncertainty of measurement:** The uncertainties of measurement are calculated by the laboratory based on application of criteria given by OD-5014 for test equipment and application of test methods, decision sheets and operational procedures of IECEE. IEC Guide 115 provides guidance on the application of measurement uncertainty principles and applying the decision rule when reporting test results within IECEE scheme, noting that the reporting of the measurement uncertainty for measurements is not necessary unless required by the test standard or customer. Calculations leading to the reported values are on file with the NCB and testing laboratory that conducted the testing.	

Collateral Standard - (001) IEC 60601-1-6L

Copy of marking plate:

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

See IEC 60601-1 test report

Collateral Standard - (001) IEC 60601-1-6L

Test item particulars.....:	See IEC 60601-1 test report
Classification of installation and use.....:	See IEC 60601-1 test report
Supply Connection.....:	See IEC 60601-1 test report
.....:	
Possible test case verdicts:	
- test case does not apply to the test object.....:	N/A
- test object does meet the requirement.....:	P (Pass)
- test object does not meet the requirement.....:	F (Fail)
Testing.....:	N/A
Date of receipt of test item .....:	N/A
Date (s) of performance of tests .....:	N/A

General remarks:

"(See Enclosure #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:

The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided ..... :	☐ **Yes** ☒ **Not applicable**

When differences exist; they shall be identified in the General product information section.

Name and address of factory (ies) ..... : See IEC 60601-1 test report.

General product information and other remarks:

See IEC 60601-1 test report

Collateral Standard - (001) IEC 60601-1-6L

IEC 60601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
4	**GENERAL REQUIREMENTS**		Pass
4.2	USABILITY ENGINEERING PROCESS complies with IEC 62366-1 including amended definitions. Excludes production and post-production monitoring, and maintenance of the USABILITY ENGINEERING PROCESS	See attached IEC 62366-1 ANNEX I	Pass
	Inspection of the USABILITY ENGINEERING FILE verified that the MANUFACTURER demonstrated compliance with IEC 62366-1:2015+A1:2020.		Pass
5	**ME EQUIPMENT ACCOMPANYING DOCUMENTS**		N/A
	The instructions for use shall contain a summary of the USE SPECIFICATION as specified in IEC 62366-1:2015, AMD1:2020, Clause 5.1	Component, to be evaluated in end product	N/A
	The same information is also included in the technical description, if this is provided as a separate document from instructions for use		N/A

Collateral Standard - (001) IEC 60601-1-6L

ANNEX I - IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist			
Clause	Requirement + Test	Result - Remark	Verdict
4	**PRINCIPLES**		Pass
4.1.1	The MANUFACTURER shall establish, document, implement and maintain a USABILITY ENGINEERING PROCESS, as defined in Clause 5, to provide SAFETY for the PATIENT, USER and others. The PROCESS shall address USER interactions with the MEDICAL DEVICE according to the ACCOMPANYING DOCUMENTATION		Pass
	USABILITY ENGINEERING activities for a MEDICAL DEVICE shall be planned, carried out, and documented by personnel competent on the basis of appropriate education, training, skills or experience.		Pass
	Where a documented product realization PROCESS exists, such as that described in Clause 7 of ISO 13485:2016, it shall incorporate the appropriate parts of or reference the USABILITY ENGINEERING PROCESS.		Pass
	Compliance with this subclause to exist when the requirements of this International Standard have been fulfilled.		Pass
4.1.2	To reduce use-related RISK, the MANUFACTURER shall use one or more of the following options, in the priority listed (as required by ISO 14971:2019, 7.1):	See risk management report, Doc. No.: GT-RM2013-010, version A.2	Pass
	a) inherently safe design and manufacture;		Pass
	b) protective measures in the MEDICAL DEVICE itself or in the manufacturing PROCESS; and		N/A
	c) information for SAFETY and, where appropriate, training to USERS.		N/A
4.1.3	When, in accordance with the priorities of 4.1.2, information for SAFETY is used as a RISK CONTROL measure, the MANUFACTURER shall subject this information to the USABILITY ENGINEERING PROCESS	SEE USABILITY ENGINEERING FILE, USABILITY SPECIFICATION, DOC. NO. GT-US2016-001, VERSION A/0	Pass
4.2	The results of the USABILITY ENGINEERING PROCESS are stored in the USABILITY ENGINEERING FILE .....:	SEE USABILITY ENGINEERING FILE, USABILITY SPECIFICATION, DOC. NO. GT-US2016-001, VERSION A/0	Pass
4.3	The level of effort and the choice of methods and tools used to perform the USABILITY ENGINEERING PROCESS vary based on:	SEE USABILITY ENGINEERING FILE, USABILITY SPECIFICATION, DOC. NO. GT-US2016-001, VERSION A/0	Pass
	a) the size and COMPLEXITY of the USER INTERFACE		Pass
	b) the SEVERITY of the HARM associated with the use of the MEDICAL DEVICE		Pass

Collateral Standard - (001) IEC 60601-1-6L

ANNEX I - IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist			
Clause	Requirement + Test	Result - Remark	Verdict
	c) the extent or complexity of the USE SPECIFICATION		Pass
	d) the presence of USER INTERFACE OF UNKNOWN PROVENANCE		N/A
	e) the extent of the modification to an existing MEDICAL DEVICE USER INTERFACE that had been subjected to the USABILITY ENGINEERING PROCESS		Pass
5	**USABILITY ENGINEERING PROCESS**		Pass
5.1	The MANUFACTURER shall prepare a USE SPECIFCATION. The USE SPECIFICATION shall include the following.....:	SEE USABILITY ENGINEERING FILE, USABILITY SPECIFICATION, DOC. NO. GT-US2016-001, VERSION A/0	Pass
	– intended medical indication		Pass
	– intended PATIENT population		Pass
	– intended part of the body or type of tissue applied to or interacted with		Pass
	– intended USER PROFILE		Pass
	– intended USE ENVIRONMENT		Pass
	– operating principle		Pass
5.2	The MANUFACTURER shall identify USER INTERFACE characteristics that could be related to SAFETY as part of a RISK ANALYSIS performed according to ISO 14971:2019, Clause 5.3	SEE USABILITY ENGINEERING FILE, USABILITY SPECIFICATION, DOC. NO. GT-US2016-001, VERSION A/0, chapter 2.3.9	Pass
5.3	As part of this RISK ANALYSIS, the MANUFACTURER shall identify known or foreseeable HAZARDS and HAZARDOUS SITUATIONS which could affect PATIENTS, USERS or others, related to the use of the MEDICAL DEVICE.	See Appended Table 5.3	Pass
5.4	The RISK ANALYSIS includes a description of all the reasonably foreseeable HAZARD-RELATED USE SCENARIOS associated with the identified HAZARD and HAZARDOUS SITUATIONS.	SEE USABILITY ENGINEERING FILE, USABILITY SPECIFICATION, DOC. NO. GT-US2016-001, VERSION A/0, chapter 2.3.9	Pass
	The description of each identified HAZARD-RELATED USE SCENARIO includes all TASKS and their sequences		Pass
	The SEVERITY of the possible resulting associated HARM was determined		Pass
5.5	The MANUFACTURER shall select the HAZARD-RELATED USE SENARIOS to be included in a SUMMATIVE EVALUATION as part of the USABILITY FILE. This SUMMATIVE EVALUATION shall include:	SEE USABILITY ENGINEERING FILE, USABILITY VALIDATION, DOC. NO. GT-UV2016-001, VERSION A/0	Pass
	- all HAZARD-RELATED USE SCENARIOS;		Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	- a subset of the HAZARD-RELATED USE SCENARIOS based on the SEVERITY of the potential HARM that could be caused by USE ERROR (e.g. for which medical intervention would be needed); or		N/A
	- a subset of the HAZARD-RELATED USE SCENARIOS based on the SEVERITY of the potential HARM and based on other circumstances specific to the MEDICAL DEVICE and the MANUFACTURER		Pass
	A summary of any selection scheme, the rationale for its use and the results of applying it shall be stored in the USABILITY ENGINEERING FILE	SEE USABILITY ENGINEERING FILE, USABILITY VALIDATION, DOC. NO. GT-UV2016-001, VERSION A/0	Pass
5.6	The MANUFACTURER shall establish and maintain a USER INTERFACE SPECIFICATION	See Appended Table 5.6	Pass
5.7	The MANUFACTURER shall establish and maintain a USER INTERFACE EVALUATION plan for the USER INTERFACE	See Appended Table 5.7	Pass
5.8	The MANUFACTURER shall design and implement the USER INTERFACE, including the ACCOMPANYING DOCUMENTATION if needed, and training capability, if needed, as described in the USER INTERFACE SPECIFICATION .....:	SEE USABILITY ENGINEERING FILE, USABILITY SPECIFICATION, DOC. NO. GT-US2016-001, VERSION A/0, chapter 2.3.8	Pass
	Where new USE ERRORS, HAZARDS, HAZARDOUS SITUATIONS or HAZARD-RELATED USE SCENARIOS are discovered during this step the MANUFACTURER shall repeat the steps of Clause 5 as appropriate	No such condition	N/A
	If training on the specific MEDICAL DEVICE is required for the safe us of the MEDICAL DEVICE by the intended USER, the MANUFACTURER shall design and implement a training capability for the EXPECTED SERVICE LIFE of the MEDICAL DEVICE by doing at least one of the following:	No training required	N/A
	- provide the materials necessary for training;		N/A
	- ensure the materials necessary for training are available;		N/A
	- make the training available; or		N/A
	- make training available to the RESPONSIBLE ORGANIZATION that enables it to train its USERS		N/A
5.9	The MANUFACTURER shall perform a SUMMATIVE EVALUATION of each HAZARD-RELATED USE SCENARIO selected in Clause 5.5	SEE USABILITY ENGINEERING FILE, USABILITY VALIDATION, DOC. NO. GT-UV2016-001, VERSION A/0, chapter 4	Pass
	All USE ERRORS and use difficulties that occurred shall be identified		Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	Where USE ERROR or use difficulty can lead to a HAZARDOUS SITUATION the root causes should be determined		Pass
	If new USE ERRORS, HAZARDS, HAZARDOUS SITUATIONS or HAZARD-RELATED USE SCENARIOS are discovered during this data analysis:		–
	- if yes, then the MANUFACTURER shall repeat the activities of Clause 5 as appropriate;		N/A
	- if not, then the MANUFACTURER determine whether further improvement of the USER INTERFACE design as it relates to SAFETY is necessary and practicable		Pass
	1) If yes, then the MANUFACTURER shall re-enter the USABILITY ENGINEERING PROCESS at Clause 5.6		N/A
	2) If not then the MANUFACTURER shall:	SEE USABILITY ENGINEERING FILE, USABILITY VALIDATION, DOC. NO. GT-UV2016-001, VERSION A/0, chapter 4	Pass
	i) Document why improvement is not necessary or not practicable;		Pass
	ii) Identify the data from the USABILITY ENGINEERING PROCESS needed to determine the RESIDUAL RISK related to use; and		Pass
	iii) Evaluate the RESIDUAL RISK according to ISO 14971:2019, Clause 7.3		Pass
5.10	USER INTERFACE OF UNKNOWN PROVENANCE (UOUP) was evaluated according to Annex C rather than the requirements of 5.1 through 5.9.	See Appended Annex C below	N/A

Annex C	**Evaluation of a USER INTERFACE OF UNKNOWN PROVENANCE (UOUP)**		N/A
C.2.1	The MANUFACTURER shall establish a USE SPECIFICATION as required in 5.1.	No UOUP	N/A
C.2.2	The MANUFACTURER of a device with UOUP shall review POST-PRODUCTION information including complaints and field reports for incidents and near incidents. All identified cases of USE ERROR shall be stored in the USABILITY ENGINEERING FILE and addressed in C.2.3 and C.2.4		N/A
C.2.3	The MANUFACTURER shall review the RISK ANALYSIS of the MEDICAL DEVICE with UOUP and ensure that all HAZARDS and HAZARDOUS SITUATIONS associated with USABILITY have been identified and documented		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
C.2.4	The MANUFACTURER shall verify and document that adequate RISK CONTROL measures have been implemented for all identified HAZARDS and HAZARDOUS SITUATIONS identified in C.2.3 and that all RISKS are reduced to an acceptable level as indicated by the RISK ASSESSMENT		N/A
C.2.5	Based on any new information identified in performing steps C.2.3 and C.2.4 the MANUFACTURER re-evaluated the overall RESIDUAL RISK according to ISO 14971:2019, Clause 7.3 and documented the results in either the USABILITY ENGINEERING FILE or RISK MANAGEMENT FILE		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

Table 5.3	**USABILITY ENGINEERING FILE RESULTS TABLE: RISK ANALYSIS**		**Pass**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
An identification of known or foreseeable HAZARDS and HAZARDOUS SITUATIONS which could affect PATIENTS, USERS or others, related to the use of the MEDICAL DEVICE. was performed according to ISO 14971:2019, Clause 5.4	See USABILITY ENGINEERING FILE, USABILITY SPECIFICATION, DOC. NO. GT-US2016-001, VERSION A/0, chapter 2.3.9	Risk analysis related usability	Pass
During the identification of HAZARDS and HAZARDOUS SITUATIONS, the following was considered:			—
– USE SPECIFICATION, including USER PROFILE(S) (See 5.1)	See USABILITY ENGINEERING FILE, USABILITY SPECIFICATION, DOC. NO. GT-US2016-001, VERSION A/0, chapter 2.3.2	User profile	Pass
– information on HAZARDS and HAZARDOUS SITUATIONS known for existing USER INTERFACES of MEDICAL DEVICES of a similar type, if available; and	See USABILITY ENGINEERING FILE, USABILITY SPECIFICATION, DOC. NO. GT-US2016-001, VERSION A/0, chapter 2.3.9	Risk analysis related usability	Pass
– identified USE ERRORS (see 5.2).	See USABILITY ENGINEERING FILE, USABILITY SPECIFICATION, DOC. NO. GT-US2016-001, VERSION A/0, chapter 2.3.3	Analysis of Hazards and Risks Associated with use of the Device	Pass

Table 5.6	**USABILITY ENGINEERING FILE RESULTS TABLE: USER INTERFACE SPECIFICATION**		**Pass**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
USER INTERFACE SPECIFICATION	See USABILITY ENGINEERING FILE, USABILITY SPECIFICATION, DOC. NO. GT-US2016-001, VERSION A/0, chapter 1.1	specification of the intended use	Pass
The USER INTERFACE SPECIFICATION shall consider:			—
– the USE SPECIFICATION (See 5.1)	See USABILITY ENGINEERING FILE, USABILITY SPECIFICATION, DOC. NO. GT-US2016-001, VERSION A/0, chapter 2.3.9	Risk analysis related usability	Pass

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Clause	Requirement + Test	Result - Remark	Verdict

Table 5.6	**USABILITY ENGINEERING FILE RESULTS TABLE: USER INTERFACE SPECIFICATION**		**Pass**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
– the known or foreseeable USE ERRORS associated with the medical device (See 5.2); and	See USABILITY ENGINEERING FILE, USABILITY SPECIFICATION, DOC. NO. GT-US2016-001, VERSION A/0, chapter 2.3.3	Analysis of Hazards and Risks Associated with use of the Device	Pass
– the HAZARD-RELATED USE SCENARIOS (See 5.4)	See USABILITY ENGINEERING FILE, USABILITY SPECIFICATION, DOC. NO. GT-US2016-001, VERSION A/0, chapter 3.5	Analysis of Hazards and Risks Associated with use of the Device	Pass
Inputs to the USER INTERFACE SPECIFICATION shall include the following:			—
– testable technical requirements relevant to the USER INTERFACE, including the requirements for those parts of the USER INTERFACE associated with the selected RISK CONTROL measures;	SEE USABILITY ENGINEERING FILE, DOC. NO.: DOC. NO. GT-UV2016-001, VERSION A/0, CHAPTER 2	Analysis of Hazards and Risks Associated with use of the Device	Pass
– an indication as to whether ACCOMPANYING DOCUMENTATION is required; and	-	Component, to be evaluated in end-product	N/A
– an indication as to whether MEDICAL DEVICE specific training is required	-	Component, to be evaluated in end-product	N/A

Table 5.7	**USABILITY ENGINEERING FILE RESULTS TABLE: USER INTERFACE EVALUATION plan**		**Pass**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
The manufacturer shall establish and maintain a USER INTERFACE EVALUATION plan for the USER INTERFACE	See usability engineering file, Doc. No.: GT-UVPLAN2016-001, version A/0	Summary of Preliminary Analysis and Evaluations	Pass
The USER INTERFACE EVALUATION plan shall document:			—
a) the objective and identify the method of any planned FORMATIVE EVALUATIONS and SUMMATIVE EVALUATIONS	See usability engineering file, Doc. No.: GT-UVPLAN2016-001, version A/0, chapter 5	Evaluation Methods Used	Pass

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Clause	Requirement + Test	Result - Remark	Verdict

Table 5.7	**USABILITY ENGINEERING FILE RESULTS TABLE: USER INTERFACE EVALUATION plan**		**Pass**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
b) if USABILITY TESTS are employed, – document which USER GROUPS are intended to be included in the test;	See usability engineering file, Doc. No.: GT-UVPLAN2016-001, version A/0, chapter 5.2	Number and Type of Test Participants	Pass
– document the test environment and other conditions of use, based on the USE SPECIFICATION;	See usability engineering file, Doc. No.: GT-UVPLAN2016-001, version A/0, chapter 5.2	Tasks and Use Scenarios	Pass
– specify whether ACCOMPANYING DOCUMENTATION is provided during the test; and	-	Component, to be evaluated in end-product	N/A
– specify whether MEDICAL DEVICE-specific training is provided prior to the test and the minimum elapsed time between the training and the beginning of the test.	-	No training required	N/A
The USER INTERFACE evaluation plan for FORMATIVE EVALUATION shall address:			—
a) the evaluation methods being used;	See usability engineering file, Doc. No.: GT-UVPLAN2016-001, version A/0, chapter 5	Evaluation Methods Used	Pass
b) which part of the USER INTERFACE is being evaluated; and	See usability engineering file, Doc. No.: GT-UVPLAN2016-001, version A/0, chapter 5.1	Key Results and Design Modifications Implemented	Pass
c) when in the USABILITY ENGINEERING PROCESS to perform each of the USER INTERFACE EVALUATIONS.	See usability engineering file, Doc. No.: GT-UVPLAN2016-001, version A/0, chapter 5.1	Key Results and Design Modifications Implemented	Pass
For each selected HAZARD-RELATED USE SCENARIO (see 5.5), the USER INTERFACE EVALUATION plan for SUMMATIVE EVALUATION shall specify:			—
a) the evaluation method being used and a rationale that the method produces OBJECTIVE EVIDENCE;	See usability engineering file, Doc. No.: GT-UV2016-001, version A/0, chapter 2	Validation result	Pass
b) which part of the USER INTERFACE is being evaluated;	See usability engineering file, Doc. No.: GT-UV2016-001, version A/0, chapter 2	Validation result	Pass
c) where applicable, the criteria for determining whether the information for SAFETY is perceivable, understandable and supports CORRECT USE of the MEDICAL DEVICE (4.1.3);	See usability engineering file, Doc. No.: GT-UV2016-001, version A/0, chapter 2.2	Simulated use scenarios and usability validation	Pass

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Clause	Requirement + Test	Result - Remark	Verdict

Table 5.7	**USABILITY ENGINEERING FILE RESULTS TABLE: USER INTERFACE EVALUATION plan**		**Pass**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
d) the availability of the ACCOMPANYING DOCUMENTATION and provision of training during the SUMMATIVE EVALUATION; and	-	No training required	N/A
e) for a USABILITY TEST, – how the characteristics of the test participants are representative of the intended USER PROFILES;	See usability engineering file, Doc. No.: GT-UV2016-001, version A/0, chapter 2.2	Simulated use scenarios and usability validation	Pass
– justifying how the test participants are grouped into distinct USER GROUPS for the purpose of determining the number of test participants;	See usability engineering file, Doc. No.: GT-UV2016-001, version A/0, chapter 2.2	Simulated use scenarios and usability validation	Pass
– the test environment and conditions of use and a rationale for how they are adequately representative of the intended USE ENVIRONMENT;	See usability engineering file, Doc. No.: GT-UV2016-001, version A/0, chapter 2.2	Simulated use scenarios and usability validation	Pass
– the definition of CORRECT USE for each HAZARD-RELATED USE SCENARIO; and	See usability engineering file, Doc. No.: GT-UV2016-001, version A/0, chapter 2.2	Simulated use scenarios and usability validation	Pass
– the method of collecting data during the USABILITY TEST for the subsequent analysis of observed USE ERRORS and use difficulties.	See usability engineering file, Doc. No.: GT-UV2016-001, version A/0, chapter 2.2.2	Usability validation result	Pass

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Collateral Standard - (002) IEC 60601-1-11G

Test Report issued under the responsibility of:

UL Solutions

TEST REPORT
IEC 60601-1-11
Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Report Number.....:	**E341350-D1012 (IEC 60601-1-11)**
Date of issue.....:	**See IEC 60601-1 test report**
Total number of pages .....:	**31**
Name of Testing Laboratory preparing the Report .....:	**UL-CCIC Company Limited Guangzhou Branch**
Applicant's name .....:	**See IEC 60601-1 test report**
Address.....:	**See IEC 60601-1 test report**
Test specification:	
Standard .....:	IEC 60601-1-11:2015, IEC 60601-1-11:2015/AMD1:2020 for use in conjunction with IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
Test procedure .....:	CB Scheme
Non-standard test method .....:	N/A
TRF template used.....:	IECEE OD-2020-F1:2021, Ed.1.4
Test Report Form No. .....:	IEC60601_1_11G
Test Report Form(s) Originator ....:	UL(US)
Master TRF .....:	2021-09-16

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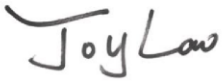
If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed.

This report is not valid as a CB Test Report unless signed by an approved IECEE Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

General disclaimer:

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This report shall not be reproduced, except in full, without the written approval of the Issuing NCB. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.

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Test item description ..... :	See IEC 60601-1 test report		
Trade Mark(s) ..... :	See IEC 60601-1 test report		
Manufacturer ..... :	See IEC 60601-1 test report		
Model/Type reference ..... :	See IEC 60601-1 test report		
Ratings ..... :	See IEC 60601-1 test report		
Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):			
☒ **CB Testing Laboratory:**	UL-CCIC Company Limited Guangzhou Branch		
Testing location/ address.....:	Room 101 & 401, Block A, R&D Building, Room 101, 201, 301, & 401, Block B, Electronic Building, No.8, Nanyun Er Road, Huangpu District Guangzhou China		
Tested by (name, function, signature).....:	Skye Mo, Project handler		
Approved by (name, function, signature)...:	Joy Lao, Project reviewer		
☐ **Testing procedure: CTF Stage 1:**			
Testing location/ address.....:			
Tested by (name, function, signature).....:			
Approved by (name, function, signature)...:			
☐ **Testing procedure: CTF Stage 2:**			
Testing location/ address.....:			
Tested by (name + signature).....:			
Witnessed by (name, function, signature) .:			
Approved by (name, function, signature)...:			
☐ **Testing procedure: CTF Stage 3:**			
☐ **Testing procedure: CTF Stage 4:**			
Testing location/ address.....:			
Tested by (name, function, signature).....:			
Witnessed by (name, function, signature) .:			
Approved by (name, function, signature)...:			
Supervised by (name, function, signature) :			

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List of Attachments (including a total number of pages in each attachment): See IEC 60601-1 test report	
Summary of testing:	
Tests performed (name of test and test clause): ENVIRONMENTAL OPERATING CONDITIONS (IEC 60601-1-11, Sub-Clause 4.2.3.1) ENVIRONMENTAL CONDITIONS OF TRANSPORT AND STORAGE BETWEEN USES (IEC 60601-1-11, Sub-Clause 4.2.2) BROAD-BAND RANDOM VIBRATION TEST (IEC 60068-2-64:2008) (IEC 60601-1-11 SUBCLAUSES: 10.1.2b) and 10.1.3c) SHOCK TEST (IEC 60068-2-27:2008) (IEC 60601-1-11 SUBCLAUSES: 10.1.2 a) and 10.1.3a))	**Testing location:** UL-CCIC Company Limited Guangzhou Branch / Room 101 & 401, Block A, R&D Building, Room 101, 201, 301, & 401, Block B, Electronic Building, No.8, Nanyun Er Road, Huangpu District Guangzhou China
Following test conducted as part of IEC 60601-1, see IEC 60601-1 report for details. INGRESS OF WATER OR PARTICULATE MATTER INTO ME EQUIPMENT (IEC 60601-1-11, Sub-Clause 8.3.1)	UL-CCIC Company Limited Guangzhou Branch / Room 101 & 401, Block A, R&D Building, Room 101, 201, 301, & 401, Block B, Electronic Building, No.8, Nanyun Er Road, Huangpu District Guangzhou China
Summary of compliance with National Differences (List of countries addressed): None. ☐ **~~The product fulfils the requirements of _____ (insert standard number and edition and delete the text in parenthesis, leave it blank or delete the whole sentence, if not applicable)~~**	

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Use of uncertainty of measurement for decisions on conformity (decision rule) :

☒ No decision rule is specified by the IEC standard, when comparing the measurement result with the applicable limit according to the specification in that standard. The decisions on conformity are made without applying the measurement uncertainty ("simple acceptance" decision rule, previously known as "accuracy method").

☐ Other:… (to be specified, for example when required by the standard or client, or if national accreditation requirements apply)

Information on uncertainty of measurement:
The uncertainties of measurement are calculated by the laboratory based on application of criteria given by OD-5014 for test equipment and application of test methods, decision sheets and operational procedures of IECEE.
IEC Guide 115 provides guidance on the application of measurement uncertainty principles and applying the decision rule when reporting test results within IECEE scheme, noting that the reporting of the measurement uncertainty for measurements is not necessary unless required by the test standard or customer.
Calculations leading to the reported values are on file with the NCB and testing laboratory that conducted the testing.

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Copy of marking plate:

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

See IEC 60601-1 test report.

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Test item particulars.....:	See IEC 60601-1 test report
Classification of installation and use.....:	See IEC 60601-1 test report
Supply Connection.....:	See IEC 60601-1 test report
.....:	
Possible test case verdicts:	
- test case does not apply to the test object.....:	N/A
- test object does meet the requirement.....:	P (Pass)
- test object does not meet the requirement.....:	F (Fail)
Testing.....:	
Date of receipt of test item .....:	2024-08-08
Date (s) of performance of tests .....:	2024-09-10 to 2024-09-20

General remarks:

"(See Enclosure #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

☐ **This Test Report Form contains requirements according to IEC/ISO ..... Standard dated ..... and includes** Corrigendum dated .....
(Note: The above text maybe removed if not applicable)

Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:

The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided ..... :	☐ **Yes** ☒ **Not applicable**

When differences exist; they shall be identified in the General product information section.

Name and address of factory (ies) ..... : See IEC 60601-1 test report.

General product information and other remarks:

See IEC 60601-1 test report.

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IEC 60601-1-11			
Clause	Requirement + Test	Result - Remark	Verdict
4	**GENERAL REQUIREMENTS**		Pass
4.1	Characteristics of SUPPLY MAINS specified in 4.10.2 of Part 1 applied, except ME EQUIPMENT or ME SYSTEMS intended for HOME HEALTHCARE ENVIRONMENT complied with the following:	**See below**	Pass
	– SUPPLY MAINS in the HOME HEALTHCARE ENVIRONMENT did not exceed 110 % or was not below 85 % of NOMINAL voltage between any of the conductors of the system or between any of these conductors and earth (% V) .....:	Rating: 100-240V~ Testing voltage: 85 - 264V~	—
	– For ME EQUIPMENT OR ME SYSTEMS intended to actively keep alive or resuscitate a PATIENT, SUPPLY MAINS in the HOME HEALTHCARE ENVIRONMENT did not exceed 110 % or was not below 80 % of NOMINAL voltage between any of the conductors of the system or between any of these conductors and earth (% V.....:	Not life-supporting ME equipment or ME system.	—
	- RATED range of NOMINAL voltage did include at least 12.4 V to 15.1 V for operation from a 12 V dc supply mains		N/A
	- RATED range of NOMINAL voltage did include at least 24.8 V to 30.3 V for operation from a 12 V dc supply mains		N/A
	The equipment maintained BASIC SAFETY and ESSENTIAL PERFORMANCE during and following a 30 s dip to 10 V from a 12 V dc SUPPLY MAINS		N/A
	The equipment maintained BASIC SAFETY and ESSENTIAL PERFORMANCE during and following a 30 s dip to 20 V from a 24 V dc SUPPLY MAINS		N/A
4.2.2	**Environmental conditions of transport and storage between uses, indicated in instructions for use**		Pass
	ME EQUIPMENT, except STATIONARY EQUIPMENT, after being removed from its protective packaging, and subsequently between uses, operated within its specified NORMAL USE after transport or storage in the specified environmental conditions		Pass
	temperature range:-25 °C to + 5 °C	-30 °C to + 80 °C	N/A
	temperature range:+5 °C to +35 °C at a non-condensing relative humidity up to 90 %	-30 °C to + 80 °C, 0 to 95% RH	N/A
	temperature range: >35 °C to 70 °C at a water vapour pressure up to 50 hPa	-30 °C to + 80 °C	N/A

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IEC 60601-1-11			
Clause	Requirement + Test	Result - Remark	Verdict
	For more restricted range of environmental transport and storage conditions between uses, the environmental conditions are specified	-30 °C to + 80 °C, 0 to 93% RH, 50kPa to 106kPa	Pass
	– Justified in the RISK MANAGEMENT FILE	See RISK MANAGEMENT Table 4.2.2	N/A
	– Marked on the ME EQUIPMENT		N/A
	When not practicable, the more restricted range is disclosed in the instructions for use		N/A
	– Marked on the carrying case when the instructions for use indicate the ME EQUIPMENT is intended to be transported or stored in a carrying case between uses		N/A
	Symbol 5.3.5 (ISO 7000-0534), 5.3.6 (ISO 7000-0533), or 5.3.7 (ISO 7000-0632) of ISO 15223-1:2016 used to mark temperature range		N/A
	Symbol 5.3.8 (ISO 7000-2620) of ISO 15223-1:2016 used to mark humidity range		N/A
	Symbol 5.3.9 (ISO 7000-2621) of ISO 15223-1:2016 used to mark atmospheric pressure range		N/A
	Where ME EQUIPMENT used different marking for conditions of transport and storage between uses, continuous operating conditions and transient operating conditions, markings accompanied by supplementary markings except where the respective applicability was obvious		N/A
	Environmental transport and storage test		Pass
	a) ME EQUIPMENT prepared for transportation or storage according to instructions for use		Pass
	b) ME EQUIPMENT exposed to its lowest specified environmental transport and storage conditions (temperature $^{0}_{-4}$ °C) (°C) .....:	-30°C, 16 hours	Pass
	– For at least 16 h or, ensure ME EQUIPMENT reached THERMAL STABILITY for at least 2 h		Pass
	c) Then ME EQUIPMENT exposed to 34 °C ± 4 °C and 90 % - 0% + 6% relative humidity until the test chamber reached equilibrium and held for at least 2 hours. The transition from low to high temperature was made slowly enough to provide a non-condensing environment.	34°C, 90%, 2 hours	Pass
	d) ME EQUIPMENT exposed to its highest specified environmental transport and storage conditions, not requiring a water vapour pressure greater than 50 hPa (temperature $^{+4}_{0}$ °C); (°C, ± %) .....:	80°C, 15%, 16 hours	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	– For at least 16 h or, ensured ME EQUIPMENT reached THERMAL STABILITY for at least 2 h		Pass
	e) At the end of this conditioning period, ME EQUIPMENT allowed to return and stabilize at the operating conditions of NORMAL USE		Pass
	f) ME EQUIPMENT evaluated to its specifications and ensured it provides BASIC SAFETY and ESSENTIAL PERFORMANCE		Pass
4.2.3.1	**Environmental operating conditions - Continuous operating conditions**		Pass
	Instructions for use indicated permissible environmental operating conditions of the ME EQUIPMENT	Temperature: -20°C to +40°C Relative Humidity: ≤ 95%, no condensation, Atmospheric Pressure: 54kPa to 106kPa	Pass
	ME EQUIPMENT complied with its specifications and all requirements of the standard when operated in NORMAL USE within temperature + 5 °C to +40 °C,	-20°C to +40°C	Pass
	Relative humidity range of 15 % to 90%, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa; and	≤95%, no condensation	N/A
	An atmospheric pressure range of 700 hPa to 1060 hPa	54kPa to 106kPa	N/A
	For more restricted range of environmental operating conditions		N/A
	- justified in the risk management file;	See RISK MANAGEMENT Table 4.2.3.1	N/A
	-marked on the equipment; or were nor practical in the instructions for use……:		N/A
	– Marked on the carrying case when the instructions for use indicate the ME EQUIPMENT is intended to be operated in a carrying case		N/A
	Symbol 5.3.5 (ISO 7000-0534), 5.3.6 (ISO 7000-0533), or 5.3.7 (ISO 7000-0632) of ISO 15223-1:2016 used to mark temperature range		N/A
	Symbol 5.3.8 (ISO 7000-2620) of ISO 15223-1:2016 used to mark humidity range		N/A
	Symbol 5.3.9 (ISO 7000-2621) of ISO 15223-1:2016 used to mark atmospheric pressure range		N/A
	Where ME EQUIPMENT used different marking for conditions of continuous operating conditions and transient operating conditions, markings accompanied by supplementary markings		N/A
	Environmental operating conditions test		Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	a) ME EQUIPMENT was set up for operation according to INTENDED USE		Pass
	b) ME EQUIPMENT exposed to 20 °C ± 4 °C for at least 6 h or, ensured ME EQUIPMENT reached THERMAL STABILITY for at least 2 h, (h) .....:	20°C, 6hrs	Pass
	c) ME EQUIPMENT evaluated to its specifications and ensured it continued to provide BASIC SAFETY and ESSENTIAL PERFORMANCE		Pass
	d) ME EQUIPMENT evaluated to its specifications and ensured it continued to provide BASIC SAFETY and ESSENTIAL PERFORMANCE while at the lowest specified atmospheric pressure.	540hPa(+)	Pass
	e) ME EQUIPMENT evaluated to its specifications and ensured it continued to provide BASIC SAFETY and ESSENTIAL PERFORMANCE while at the highest specified atmospheric pressure.	1060hPa(+)	Pass
	f) Pressure in chamber relieved		Pass
	g) ME EQUIPMENT cooled to its lowest specified environmental operating conditions		Pass
	h) ME EQUIPMENT held at lowest specified environmental operating conditions for at least 6 h or, ensured the ME EQUIPMENT reached THERMAL STABILITY for at least 2 h .....:	-20°C, 6hrs	Pass
	i) ME EQUIPMENT met its specifications and BASIC SAFETY and ESSENTIAL PERFORMANCE		Pass
	j) ME EQUIPMENT warmed to its highest specified continuous environmental operating conditions		Pass
	k) ME EQUIPMENT held the conditions of j) for at least 6 h or, ensured the ME EQUIPMENT reached THERMAL STABILITY for at least 2 h .....:	40°C, 95%RH, 6hrs	Pass
	l) ME EQUIPMENT met its specifications and BASIC SAFETY and ESSENTIAL PERFORMANCE		Pass
4.2.3.2	**Environmental shock to TRANSIT-OPERABLE EQUIPMENT**		N/A
	TRANSIT-OPERABLE EQUIPMENT with a stated wider range of continuous environmental operation conditions maintained BASIC SAFETY and ESSENTIAL PERFORMANCE in the presence of condensation and thermal shock from rapid changes in environmental temperature and humidity during INTENDED USE when test in accordance with 4.2.3.2 a)-j).	No transit-operable equipment	N/A

5	**GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT**	Pass
	In addition to the requirements of 5.9.2.1 of with IEC 60601-1 standard, accessibility determined as indicated below:	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	ACCESSIBLE parts of ME EQUIPMENT identified by inspection and, when necessary, by testing	Inspection and testing	Pass
	When in doubt, an ACCESSIBLE PART of ME EQUIPMENT determined by a test with the small finger probe of Fig 1, applied in a bent or straight position as follows:	See IEC 60601-1 clause 5.9.2	Pass
	– for all positions of the ME EQUIPMENT operating in NORMAL USE		Pass
	– after opening ACCESS COVERS and removal of parts, including lamps, fuses, and fuse holders when:	No such condition	N/A
	i) the ACCESS COVERS could be opened without the use of a TOOL, or		N/A
	ii) the instructions for use instructed a LAY OPERATOR to open the relevant ACCESS COVER		N/A
6	**CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS**		Pass
	ME EQUIPMENT intended for HOME HEALTHCARE ENVIRONMENT classified as follows, except for PERMANENTLY INSTALLED EQUIPMENT and as required by Part 1, Sub-clause 6.2:	See below	Pass
	– CLASS II or INTERNALLY POWERED .....:	Class II	Pass
	– Not provided with a FUNCTIONAL EARTH TERMINAL		Pass
	– When equipped with APPLIED PARTS, they are TYPE BF or CF .....:	Component only, to be evaluated in end product.	N/A
7	**ME EQUIPMENT IDENTIFICATION, MARKING AND DOCUMENTS**		Pass
7.1	USABILITY of identification, marking, and ACCOMPANYING DOCUMENTS intended for LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION evaluated by an OPERATOR whose PROFILE included minimum eight years of education	Refer to Usability validation plan, GT-UVPLAN2016-001, version A/0, chapter 5.2.1	Pass
	ME EQUIPMENT and ME SYSTEMS intended for HOME HEALTHCARE ENVIRONMENT are simple to use and do not require referencing complex ACCOMPANYING DOCUMENTS..... :	Component, to be evaluated in end product	N/A
7.2	In addition to requirements of 7.2.9 of the general standard, the ME EQUIPMENT or its parts and, when appropriate, a carrying case are marked with the appropriate IP classification as tested in 8.3.1 .. :	No carrying case	N/A
	If the carrying case provide some or all of the ingress protection against water or particulate matter:	No carrying case	N/A
	a) The ENCLOSURE is marked with the safety sign ISO 7010-W001 and “keep dry” or symbol ISO 15223-1:2012, 5.3.4 (ISO 7000-0626) ..... :	No carrying case	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	b) the carrying case marked with its degree of protection..... :	No carrying case	N/A
	Carrying case inspected, and tests and criteria of 7.1.2 and 7.1.3 of Part 1 applied ..... :	No carrying case	N/A
7.3	ACCOMPANYING DOCUMENTS		N/A
7.3.1	ACCOMPANYING DOCUMENTS indicate the LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION contact the MANUFACTURER or MANUFACTURER'S representative on the following issues:	Component only, to be evaluated in end product.	N/A
	– Assistance in setting up, using, or maintaining the ME EQUIPMENT or ME SYSTEM when needed, or		N/A
	– To report unexpected operation or events		N/A
	ACCOMPANYING DOCUMENTS include a postal address and either a phone number or web address for the LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION to contact the MANUFACTURER or MANUFACTURER'S representative		N/A
7.3.2	ACCOMPANYING DOCUMENTS include necessary details for healthcare professional to brief the LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION on any known contraindication(s) to the use of ME EQUIPMENT or ME SYSTEM and any precautions to be taken, including the following:	Component only, to be evaluated in end product.	N/A
	– Precautions to be taken in the event of changes in the performance of ME EQUIPMENT or ME SYSTEM		N/A
	– Precautions to be taken regarding the exposure of the ME EQUIPMENT or ME SYSTEM to reasonably foreseeable environmental conditions		N/A
	– Adequate information regarding medicinal substances that ME EQUIPMENT is designed to administer, including any limitations in the choice of substances to be delivered as indicated below:		N/A
	– Information on any medicinal substances or human blood derivatives incorporated into the ME EQUIPMENT or ACCESSORIES as an integral part; and		N/A
	– The degree of accuracy claimed for ME EQUIPMENT with a measuring FUNCTION		N/A
7.4	**Instructions for use**		N/A
7.4.1	Nature of the HAZARD, likely consequences that could occur if the advice is not followed, and precautions for reducing the RISK described in instructions for use corresponding to each warning and SAFETY SIGN ..... :	Component only, to be evaluated in end product.	N/A
	The instructions for use address the following issues, as applicable:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– Strangulation due to cables and hoses, particularly due to excessive length		N/A
	– Inhalation or swallowing of small parts		N/A
	– Potential allergic reactions to accessible materials used in the ME EQUIPMENT		N/A
	– Contact injuries		N/A
	The instructions for use include warnings to the effect that the following actions could be unsafe as applicable:		N/A
	– Use of ACCESSORIES, detachable parts, and materials not described in the instructions for use (see 7.9.2.14 of Part 1)		N/A
	– Interconnection of this equipment to other equipment not described in the instructions for use (see 16.2 c) indent 9) of Part 1)		N/A
	– Modification of the equipment		N/A
	– Use of the ME EQUIPMENT outside its carrying case when some part of the protection required by this standard is provided by that carrying case (see 8.3.1 and 10.1)		N/A
7.4.2	When BASIC SAFETY or ESSENTIAL PERFORMANCE dependents on the INTERNAL ELECTRICAL POWER SOURCE, the instructions for use describes the following:	Component only, to be evaluated in end product.	N/A
	– Typical operation time or number of procedures .. :		N/A
	– Typical service life of the INTERNAL ELECTRICAL POWER SOURCE; and ..... :		N/A
	– Behaviour of ME EQUIPMENT while the rechargeable INTERNAL ELECTRICAL POWER SOURCE is charging ..... :		N/A
7.4.3	Instructions for use for ME EQUIPMENT intended for use by a LAY OPERATOR include easily understood diagrams, illustrations, or photographs of the fully assembled and ready-to-operate ME EQUIPMENT including all controls, visual INFORMATION SIGNALS, and indicators provided (see 7.1)		N/A
7.4.4	**Additional requirements for ME EQUIPMENT start-up PROCEDURE:**		N/A
	– Easily understood diagrams, illustrations, or photographs showing proper connection of the PATIENT to the ME EQUIPMENT, ACCESSORIES and other equipment (see 7.1)	Component only, to be evaluated in end product.	N/A
	– the time from switching "ON" until the ME EQUIPMENT is ready for NORMAL USE, when it exceeds 15 s (see 15.4.4 of Part 1) (s) ..... :	Component only, to be evaluated in end product.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	-the time required for ME EQUIPMENT to warm from the minimum storage temperature between uses until it is ready for intended use; and ..... :		N/A
	-the time required for ME EQUIPMENT to cool from the maximum storage temperature between uses until it is ready for intended use; and ..... :		N/A
7.4.5	Instructions for use for ME EQUIPMENT intended for use by a LAY OPERATOR include a description of generally known conditions in the HOME HEALTHCARE ENVIRONMENT that can unacceptably affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the ME EQUIPMENT	Component only, to be evaluated in end product.	N/A
	The steps that can be taken by the LAY OPERATOR to identify and resolve the above conditions		N/A
	At least the following issues are also included as applicable		N/A
	- The effects of lint, dust, light (including sunlight), etc.		N/A
	- A list of known devices or other sources that can potentially cause interference problems		N/A
	- The effects of degraded sensors and electrodes, or loosened electrodes, that can degrade performance or cause other problems		N/A
	- The effects caused by pets, pests or children		N/A
	The instructions for use explain the meaning of the IP classification marked on the ME EQUIPMENT, and on any carrying case provided with the ME EQUIPMENT as applicable		N/A
7.4.6	Instructions for use include a troubleshooting guide for use when there are indications of a ME EQUIPMENT malfunction during start-up or operation	Component only, to be evaluated in end product.	N/A
	Troubleshooting guide discloses the necessary steps in the event of an TECHNICAl ALARM CONDITION		N/A
7.4.7	Instructions for use for ME EQUIPMENT, ME SYSTEMS, parts, and ACCESSORIES for other than single use that can be contaminated by contact with PATIENT, body fluids, or expired gases, during INTENDED USE, indicate the following:		N/A
	– Frequency of cleaning, cleaning and disinfection, or cleaning and sterilization, as appropriate, for ME EQUIPMENT, ME SYSTEMS, parts, and ACCESSORIES used on the same PATIENT including rinsing methods, drying, handling, and storage between uses (see 8.1 and 8.2); and		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– It is necessary to clean and disinfect, clean and sterilize the ME EQUIPMENT, ME SYSTEMS, parts, and ACCESSORIES for multiple PATIENT use between uses on different PATIENTS, including rinsing methods, drying, handling, and storage until re-use (see 8.1 and 8.2), or		N/A
	– ME EQUIPMENT, ME SYSTEMS and ACCESSORIES require professional hygienic maintenance prior to re-use and provide contact details for the source of these services (see 7.5.2)		N/A
7.4.8	Instructions for use include:		N/A
	– EXPECTED SERVICE LIFE of the ME EQUIPMENT .....:	Component only, to be evaluated in end product.	N/A
	– EXPECTED SERVICE LIFE of parts and ACCESSORIES shipped with the ME EQUIPMENT .....:		N/A
	– SHELF LIFE of parts and ACCESSORIES shipped with ME EQUIPMENT when SHELF LIFE is less than the EXPECTED SERVICE LIFE .....:		N/A
7.4.9	Instructions for use include:		N/A
	– A statement indicating the LAY RESPONSIBLE ORGANIZATION must contact its local authorities to determine the proper method of disposal of potentially bio hazardous parts and ACCESSORIES, as applicable	Component only, to be evaluated in end product.	N/A
7.4.10	Instructions for use includes the recommended placement of the remote parts of the DISTRIBUTED ALARM SYSTEM, when applicable, to ensure the OPERATOR can be notified at all times by an appropriate element of DISTRIBUTED ALARM SYSTEM within its specified range		N/A
7.5	**Technical description**		N/A
7.5.1	The technical description for PERMANENTLY INSTALLED CLASS I ME EQUIPMENT includes:	Component only, to be evaluated in end product.	N/A
	– A warning indicating the ME EQUIPMENT installation, including a correct PROTECTIVE EARTH CONNECTION, must only be carried out by qualified SERVICE PERSONNEL		N/A
	– Specifications of the PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR		N/A
	– A warning to verify the integrity of the external protective earthing system		N/A
	– A warning to connect and verify that the PROTECTIVE EARTH TERMINAL of the PERMANENTLY INSTALLED ME EQUIPMENT is connected to the external protective earthing system		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
7.5.2	Technical description includes methods for cleaning and disinfection or cleaning and sterilization for ME EQUIPMENT and ACCESSORIES requiring professional hygienic maintenance prior to reuse (see 7.4.7):		N/A
	– Before and after any type of service PROCEDURE		N/A
	– When the ME EQUIPMENT is transferred to another PATIENT		N/A
8	**PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS**		Pass
8.1	A LAY OPERATOR in the HOME HEALTHCARE ENVIRONMENT can perform the cleaning or cleaning and disinfection PROCESSES when intended (see 7.4.7)		Pass
	USABILITY of each such PROCESS pertaining to a LAY OPERATOR was investigated by the USABILITY ENGINEERING PROCESS .....:	See USABILITY ENGINEERING FILE, DOC. DOC. NO. GT-UV2016-001, VERSION A/0	Pass
8.2	A LAY OPERATOR in the HOME HEALTHCARE ENVIRONMENT can perform the cleaning and sterilization PROCESSES when intended (see 7.4.7)		Pass
	USABILITY of each such PROCESS pertaining to a LAY OPERATOR was investigated by the USABILITY ENGINEERING PROCESS	See USABILITY ENGINEERING FILE	Pass
8.3	**Additional requirements for ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS**		Pass
8.3.1	TRANSIT-OPERABLE, HANDHELD, and BODY-WORN ME EQUIPMENT maintained BASIC SAFETY and ESSENTIAL PERFORMANCE after undergoing the test of IEC 60529 for at least IP 22 .....:	IP22	Pass
	All other ME EQUIPMENT maintained BASIC SAFETY and ESSENTIAL PERFORMANCE after undergoing the test of IEC 60529 for at least IP21 .....:	See above	N/A
	For PORTABLE ME EQUIPMENT intended to be used only while in a carrying case, IP21 met with the ME EQUIPMENT in its the carrying case		N/A
	Maintenance of BASIC SAFETY and ESSENTIAL PERFORMANCE VERIFIED		Pass
8.3.2	ENCLOSURES of the non-ME EQUIPMENT parts of the ME SYSTEMS provide the degree of protection against harmful ingress of water or particulate matter equivalent to equipment complying with their respective IEC or ISO safety standards		N/A
	Tests of IEC 60529:1989 conducted with the equipment placed in the least favourable position of NORMAL USE and the ENCLOSURES inspected		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
8.4	**Additional requirements for interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT and ME SYSTEM**		N/A
	ME EQUIPMENT or ME SYSTEM with ESSENTIAL PERFORMANCE intended to actively keep alive or resuscitate a PATIENT maintained its ESSENTIAL PERFORMANCE for a sufficient time or for a sufficient number of PROCEDURES when loss or failure of SUPPLY MAINS or near depletion INTERNAL ELECTRICAL POWER SOURCE occurred	Not life supporting ME equipment or ME system	N/A
	The time or number of PROCEDURES remaining allowed alternative life-supporting methods to be employed		N/A
	Optionally, an INTERNAL ELECTRICAL POWER SOURCE was used to maintain ESSENTIAL PERFORMANCE .....:	No such condition	N/A
	Optionally, independent means were used to provide ESSENTIAL PERFORMANCE .....:	No ESSENTIAL PERFORMANCE	N/A
	Instructions for use disclose the time or number of procedures available following a loss or failure of the SUPPLY MAINS or near depletion of the INTERNAL ELECTRICAL POWER SOURCE		N/A
	Instructions for use describes the alternative life-supporting methods to be employed		N/A
	The technical description describes methods that can be employed for longer periods		N/A
	ME EQUIPMENT or ME SYSTEM with ESSENTIAL PERFORMANCE intended to actively keep alive or resuscitate a PATIENT with no INTERNAL ELECTRICAL POWER SOURCE is equipped with an ALARM SYSTEM that includes at least a MEDIUM PRIORITY ALARM CONDITION indicating power failure .....:	Not life supporting ME equipment or ME system	N/A
	ME EQUIPMENT or ME SYSTEM with ESSENTIAL PERFORMANCE intended to actively keep alive or resuscitate a PATIENT with an INTERNAL ELECTRICAL POWER SOURCE is equipped with an automatic switchover to INTERNAL ELECTRICAL POWER SOURCE		N/A
	ME EQUIPMENT or ME SYSTEM with ESSENTIAL PERFORMANCE intended to actively keep alive or resuscitate a PATIENT with an INTERNAL ELECTRICAL POWER SOURCE is equipped with an ALARM SYSTEM that includes at least a MEDIUM PRIORITY TECHNICAL ALARM CONDITION indicating the INTERNAL ELECTRICAL POWER SOURCE is nearing insufficient remaining power for operation		N/A
	TECHNICAL ALARM CONDITION provides sufficient time or sufficient number of procedures for a LAY OPERATOR to act		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	A TECHNICAL ALARM CONDITION of at least LOW PRIORITY remained active until the INTERNAL ELECTRICAL POWER SOURCE returned to a level above the ALARM LIMIT or until depleted		N/A
	It was not possible to inactivate the visual ALARM SIGNAL of this TECHNICAL ALARM CONDITION		N/A
	Functional tests conducted, and the RISK MANAGEMENT FILE inspected .....:	See RISK MANAGEMENT Table 8.4	N/A
8.5	**Additional requirements for an INTERNAL ELECTRICAL POWER SOURCE**		N/A
8.5.1	ME EQUIPMENT provided with a means for the OPERATOR to determine state of the INTERNAL ELECTRICAL POWER SOURCE when the is essential for BASIC SAFETY or ESSENTIAL PERFORMANCE or to control risks associated with loss of ESSENTIAL PERFORMANCE	No such condition	N/A
	State of INTERNAL ELECTRICAL POWER SOURCE indicated by:		N/A
	- number of PROCEDURES remaining;		N/A
	-remaining operating time;		N/A
	-percentage of the remaining operating time or energy; or		N/A
	-"fuel" gauge		N/A
	Instructions described method to determine state of INTERNAL ELECTRICAL POWER SOURCE		N/A
8.5.2	Means, other than labelling, provided to prevent RISK of swallowing coin/button cells		N/A
	Replacement of button cell require use of TOOL		N/A
8.5.3	For ME EQUIPMENT or ME SYSTEM with an INTERNAL ELECTRICAL POWER SOURCE, if simultaneous connection of the ME EQUIPMENT to the PATIENT and the SUPPLY MAINS is possible, then APPLIED PARTS and parts that are likely to come into contact with the PATIENT have two MOPP from the SUPPLY MAINS		N/A
	Parts which the PATIENT intentionally handles as the intended OPERATOR while the ME EQUIPMENT is not being used for its intended medical function are insulated with two MOOP or two MOPP from SUPPLY MAINS.	No such condition	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
9	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		Pass
	The RISKS associated with USABILITY in the HOME HEALTHCARE ENVIRONMENT for OPERATOR PROFILES including a LAY OPERATOR when performing the USABILITY ENGINEERING PROCESS include at least the following considerations:		Passs
	– changes of controls		N/A
	– unexpected movement		N/A
	– potential for misconnection		N/A
	– potential for improper operation, or unsafe use		Pass
	– potential for confusion as to current operational mode		Pass
	– change in the transfer of energy or substance		N/A
	- exposure to environmental conditions specified in this standard		Pass
	– exposure to biological materials, and		N/A
	– small parts being inhaled or swallowed		N/A
	Particular emphasis placed on the limited training of a LAY OPERATOR with respect to the ability to intervene and maintain BASIC SAFETY and ESSENTIAL PERFORMANCE.		Pass
	The MANUFACTURER'S USABILITY ENGINEERING PROCESS included the least capable intended LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION		Pass
	USABILITY ENGINEERING FILE inspected for compliance .....:	See USABILITY ENGINEERING FILE, DOC. NO. GT-UV2016-001, VERSION A/0	Pass

10	**CONSTRUCTION OF ME EQUIPMENT**		Pass
10.1	Additional requirements for mechanical strength		Pass
10.1.1	Additions to Table 28 Mechanical strength test of the base standard, conducted as indicated in Table 1, Mechanical strength test applicability, non-TRANSIT-OPERABLE, and Table 2, Mechanical strength test applicability, TRANSIT-OPERABLE		Pass
10.1.2	ME EQUIPMENT, its parts, and mounting ACCESSORIES, intended for non-TRANSIT-OPERABLE use displayed adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, including pushing, impact, dropping and rough handling (not applicable to FIXED and STATIONARY ME EQUIPMENT)		Pass
	ME EQUIPMENT maintained BASIC SAFETY and ESSENTIAL PERFORMANCE after mechanical tests		Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	OPERATOR-re-settable protective devices that can be reset without the use of a TOOL were, optionally, reset prior to the evaluation of BASIC SAFETY and ESSENTIAL PERFORMANCE		N/A
	a) Shock tests conducted in accordance with IEC 60068-2-27:2008 ..... :	See Appended Table 10.1.2a	Pass
	b) Broad-band random vibration tests conducted in accordance with IEC 60068-2-64:2008, using the following conditions ..... :	See Appended Table 10.1.2b	Pass
10.1.3	ME EQUIPMENT, parts, and mounting ACCESSORIES for TRANSIT-OPERABLE use displayed adequate mechanical strength when subjected to pushing, impact, dropping, rough handling, and rigorous conditions of PATIENT movement in NORMAL USE as well as transportation by trolleys, carts, road vehicles, trains, ships, and aircraft		N/A
	ME EQUIPMENT maintained BASIC SAFETY and ESSENTIAL PERFORMANCE after the following tests:		N/A
	a) Shock tests conducted on other than HAND-HELD ME EQUIPMENT, parts, and mounting ACCESSORIES in accordance with IEC 60068-2-27:2008		N/A
	1) Test type: Type 1 ..... :	See Appended Table 10.1.3a1	N/A
	2) Test type: Type 2 ..... :	See Appended Table 10.1.3a2	N/A
	b) Shock tests conducted on HAND-HELD ME EQUIPMENT, parts, and mounting ACCESSORIES in accordance with IEC 60068-2-27:2008		N/A
	1) Test type: Type 1 ..... :	See Appended Table 10.1.3b1	N/A
	2) Test type: Type 2 ..... :	See Appended Table 10.1.3b2	N/A
	c) Broad-band random vibration test conducted on ME EQUIPMENT, parts, and mounting ACCESSORIES in accordance with IEC 60068-2-64:2008 ..... :	See Appended Table 10.1.3c	N/A
	d) Free fall tests conducted on PORTABLE and MOBILE ME EQUIPMENT, parts, and mounting ACCESSORIES per IEC 60068-2-31:2008, using PROCEDURE 1 ..... :	See Appended Table 10.1.3d	N/A
	BASIC SAFETY and ESSENTIAL PERFORMANCE were maintained		Pass
10.2	Controls of ME EQUIPMENT intended for use by a LAY OPERATORY that can affect BASIC SAFETY or ESSENTIAL PERFORMANCE protected from accidental or unauthorized changes or adjustments		N/A
	OPERATOR-adjustable controls used for calibration include a means to prevent unintentional changes from the intended position		N/A

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IEC 60601-1-11			
Clause	Requirement + Test	Result - Remark	Verdict
11	**PROTECTION AGAINST STRANGULATION OR ASPHYXIATION**		Pass
	Means provided to control the RISK of strangulation and asphyxiation of the PATIENT and others to an acceptable level		Pass
	EQUIPMENT and RISK MANAGEMENT FILE inspected .... :	See RISK MANAGEMENT Table 11	Pass
12	**ADDITIONAL REQUIREMENTS FOR ELECTROMAGNETIC EMISSIONS OF ME EQUIPMENT AND ME SYSTEMS**		N/A
	ME EQUIPMENT and ME SYSTEMS intended for HOME HEALTHCARE ENVIRONMENT are Class B according to CISPR 11:2009..... :	Not evaluated by UL	N/A
13	**ADDITIONAL REQUIREMENTS FOR ALARM SYSTEMS OF ME EQUIPMENT AND ME SYSTEMS**		N/A
13.1	Each HIGH PRIORITY and MEDIUM PRIORITY ALARM CONDITION causes generation of auditory ALARM SIGNALS per IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, except when equipment is connected to a DISTRIBUTED ALARM SYSTEM intended for confirmed deliver of ALARM CONDITIONS including the generation of auditory ALARM SIGNALS per IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 ..... :	No alarm	N/A
13.2	For ME EQUIPMENT and ME SYSTEMS intended to actively keep alive or resuscitate a PATIENT, reducing the auditory ALARM SIGNAL volume T below audible levels resulted in the following was not possible, except when the ALARM SYSTEM was connected to a DISTRIBUTED ALARM SYSTEM that included generation of auditory ALARM SIGNALS per IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012		N/A

Collateral Standard - (002) IEC 60601-1-11G

IEC 60601-1-11			
Clause	Requirement + Test	Result - Remark	Verdict

4.2.2	**RM RESULTS TABLE: Permissible environmental conditions of transport and storage, between uses, indicated in instructions for use**		**N/A**
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
5.2			
5.3			
5.4			
5.5			

4.2.3.1	**RM RESULTS TABLE: Environmental operating conditions - Continuous operating conditions**		**N/A**
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
5.2			
5.3			
5.4			
5.5			

7.4.1	**RM RESULTS TABLE: Additional requirements for warning and safety notices**		**N/A**
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
5.2			
5.3			
5.4			
5.5			
6			
7.1			

7.4.5	**RM RESULTS TABLE: : Additional requirements for operating instructions**		**N/A**
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
5.4			
5.5			
6			
7.1			

Collateral Standard - (002) IEC 60601-1-11G

IEC 60601-1-11			
Clause	Requirement + Test	Result - Remark	Verdict

8.4	**RM RESULTS TABLE: Additional requirements for interruption of power supply / supply mains to ME Equipment and ME Systems**		**N/A**
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
5.2			
5.3			
5.4			
6			
7.1			
7.2			
7.3			
7.4			
7.5			
7.6			

10.1.2a	**TABLE: Shock test (IEC 60068-2-27:2008), using the following conditions*:**		**Pass**
	Peak acceleration..... :	150 m/s2 (15 g)	
	Duration ..... :	11 ms	
	Pulse shape..... :	half-sine	
	Number of shocks ..... :	3 shocks per direction per axis (18 total)	

Direction Shock Applied	**Axis Shock Applied**	**BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No**	**Remarks**
+X	X	Yes	Intact, no effect the basic safety
-X	X	Yes	Intact, no effect the basic safety
+Y	Y	Yes	Intact, no effect the basic safety
-Y	Y	Yes	Intact, no effect the basic safety
+Z	Z	Yes	Intact, no effect the basic safety
-Z	Z	Yes	Intact, no effect the basic safety

Supplementary information:

*(NOTE 1 This represents Class 7M1 as described in IEC TR 60721-4-7:2001 [6])

Collateral Standard - (002) IEC 60601-1-11G

IEC 60601-1-11			
Clause	Requirement + Test	Result - Remark	Verdict

10.1.2b	**TABLE: Broad-band random vibration test (IEC 60068-2-64:2008) using the following conditions*:**		**Pass**
1	Acceleration amplitude.....:	10 Hz to 100 Hz: 1,0 $(m/s^2)^2/Hz$	
2	Acceleration amplitude.....:	100 Hz to 200 Hz: – 3 db per octave	
3	Acceleration amplitude.....:	200 Hz to 2 000 Hz: 0,5 $(m/s^2)^2/Hz$	
	Duration .....:	30 min per perpendicular axis (3 total)	

Perpendicular axis subjected to broad-band random vibration test	**Acceleration amplitude**	**BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No**	**Remarks**
X axis	10-100 Hz Random (30 min)	Yes	Intact, no effect the basic safety
--	100-200 Hz	Yes	Intact, no effect the basic safety
--	200-2000 Hz	Yes	Intact, no effect the basic safety
Y axis	10-100 Hz Random (30 min)	Yes	Intact, no effect the basic safety
--	100-200 Hz	Yes	Intact, no effect the basic safety
--	200-2000 Hz	Yes	Intact, no effect the basic safety
Z axis	10-100 Hz Random (30 min)	Yes	Intact, no effect the basic safety
--	100-200 Hz	Yes	Intact, no effect the basic safety
--	200-2000 Hz	Yes	Intact, no effect the basic safety

Supplementary information:

* (NOTE 2 This represents Class 7M1 and 7M2 as described in IEC TR 60721-4-7:2001)

Collateral Standard - (002) IEC 60601-1-11G

IEC 60601-1-11			
Clause	Requirement + Test	Result - Remark	Verdict

10.1.3a1	**TABLE: Shock test (IEC 60068-2-27:2008) for other than HAND-HELD EQUIPMENT, parts, and mounting ACCESSORIES under the following conditions (Test Type 1):**		**N/A**
	Peak acceleration ..... :	150 m/s^2 (15 g)	
	Duration..... :	11 ms	
	Pulse shape ..... :	half-sine	
	Number of shocks..... :	3 shocks per direction per axis (18 total)	

Direction Shock Applied	**Axis Shock Applied**	**BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No**	**Remarks**

Supplementary information:
* (NOTE 3 This represents Class 7M2 as described in IEC/TR 60721-4-7:2001 [6])

Collateral Standard - (002) IEC 60601-1-11G

IEC 60601-1-11			
Clause	Requirement + Test	Result - Remark	Verdict

10.1.3a2	**TABLE: Shock test (IEC 60068-2-27:2008) on other than HAND-HELD ME EQUIPMENT, parts, and mounting ACCESSORIES under the following conditions (Test Type 2):**		**N/A**
	Peak acceleration ..... :	300 m/s^2 (15 g)	
	Duration..... :	6 ms	
	Pulse shape ..... :	half-sine	
	Number of shocks..... :	3 shocks per direction per axis (18 total)	

Direction Shock Applied	Axis Shock Applied	BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No	Remarks

Supplementary information:

Collateral Standard - (002) IEC 60601-1-11G

IEC 60601-1-11			
Clause	Requirement + Test	Result - Remark	Verdict

10.1.3b1	**TABLE: Shock test (IEC 60068-2-27:2008) on HAND-HELD ME EQUIPMENT parts, and mounting ACCESSORIES using the following conditions (Test Type 1):**		**N/A**
	Peak acceleration..... :	300 m/s² (30 g)	
	Duration ..... :	11 ms	
	Pulse shape..... :	half-sine	
	Number of shocks ..... :	3 shocks per direction per axis (18 total)	

Direction Shock Applied	Axis Shock Applied	BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No	Remarks

Supplementary information:

*(NOTE 4 This represents Class 7M3 as described in IEC/TR 60721-4-7:2001. (Test Type 1)

Collateral Standard - (002) IEC 60601-1-11G

IEC 60601-1-11			
Clause	Requirement + Test	Result - Remark	Verdict

10.1.3b2	**TABLE: Shock test (IEC 60068-2-27:2008) on HAND-HELD ME EQUIPMENT parts, and mounting ACCESSORIES using the following conditions (Test Type 2):**		**N/A**
	Peak acceleration ..... :	1000 m/s^2 (100 g)	
	Duration..... :	6 ms	
	Pulse shape ..... :	half-sine	
	Number of shocks..... :	3 shocks per direction per axis (18 total)	

Direction Shock Applied	Axis Shock Applied	BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No	Remarks
Supplementary information:			

Collateral Standard - (002) IEC 60601-1-11G

IEC 60601-1-11			
Clause	Requirement + Test	Result - Remark	Verdict

10.1.3c	**TABLE: Broad-band random vibration test (IEC 60068-2-64:2008) on ME EQUIPMENT, parts, and mounting ACCESSORIES using the following conditions*:**		**N/A**
1	Acceleration amplitude ..... :	10 Hz to 100 Hz: 1,0 $(m/s^2)^2/Hz$	
2	Acceleration amplitude ..... :	100 Hz to 200 Hz: - 3 db per octave	
3	Acceleration amplitude ..... :	200 Hz to 2 000 Hz: 0,5 $(m/s^2)^2/Hz$	
	Duration..... :	30 min per perpendicular axis (3 total)	

Perpendicular axis subjected to broad-band random vibration test	Acceleration amplitude	BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No	Remarks
1	1		
2	1		
3	1		
1	2		
2	2		
3	2		
1	3		
2	3		
3	3		

Supplementary information:

*(NOTE 5 This represents Class 7M1 and 7M2 as described in IEC/TR 60721-4-7:2001)

Collateral Standard - (002) IEC 60601-1-11G

IEC 60601-1-11			
Clause	Requirement + Test	Result - Remark	Verdict

10.1.3d	**TABLE: Free fall test (IEC 60068-2-31:2008), using PROCEDURE 1, on PORTABLE and MOBILE ME EQUIPMENT, parts, and mounting ACCESSORIES (with carrying case if intended), under the following conditions*:**		**N/A**
1	Fall height for mass ≤ 1 kg .....:	0,25 m	
2	Fall height for mass > 1 kg and ≤ 10 Kg .....:	0,1 m	
3	Fall height for mass > 10 kg and ≤ 50 Kg .....:	0,05 m	
4	Fall height for mass > 50 kg .....:	0,01 m	

Specified altitude (m)	Mass (Kg)	Fall No.	BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No	Remarks
0,25	≤ 1	1		
0,25	≤ 1	2		
0,1	> 1 & ≤ 10	1		
0,1	> 1 & ≤ 10	2		
0,05	> 10 & ≤ 50	1		
0,05	> 10 & ≤ 50	2		
0,01	> 50	1		
0,01	> 50	2		

Supplementary information:

(*NOTE 6 This represents Class 7M2 as described in IEC/TR 60721-4-7:2001**)**

11.0	**RM RESULTS TABLE: PROTECTION AGAINST STRANGULATION AND ASPHYXIATION**		**Pass**
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
5.4	RISK_MANAGEMENT_REPORT, doc. No. GT-RM2013-010, version A.2, CHAPTER 6.3	Estimation of the risk(s) for each hazardous situation. Hazard ID (No. 313)	Pass
5.5	RISK_MANAGEMENT_REPORT, doc. No. GT-RM2013-010, version A.2, CHAPTER 6.4	Risk estimation. Hazard ID (No. 30)	Pass
6	RISK_MANAGEMENT_REPORT, doc. No. GT-RM2013-010, version A.2, CHAPTER 7	Risk evaluation. Hazard ID (No. 13)	Pass
7.1	RISK_MANAGEMENT_REPORT, doc. No. GT-RM2013-010, version A.2, CHAPTER 8	Risk control option analysis Hazard ID (No. 13)	Pass

Collateral Standard - (002) IEC 60601-1-11G

IEC 60601-1-11			
Clause	Requirement + Test	Result - Remark	Verdict

11.0	**RM RESULTS TABLE: PROTECTION AGAINST STRANGULATION AND ASPHYXIATION**		**Pass**
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
7.2	RISK_MANAGEMENT_REPORT, doc. No. GT-RM2013-010, version A.2, CHAPTER 8	Implementation of risk control measures Hazard ID (No. 30)	Pass
7.3	RISK_MANAGEMENT_REPORT, doc. No. GT-RM2013-010, version A.2, CHAPTER 8.2	Residual risk evaluation Hazard ID (No. 13)	Pass
7.4	RISK_MANAGEMENT_REPORT, doc. No. GT-RM2013-010, version A.2, CHAPTER 8.3	No need to do Benefit-risk analysis	N/A
7.6	RISK_MANAGEMENT_REPORT, doc. No. GT-RM2013-010, version A.2, CHAPTER 10.1	Completeness of risk control Hazard ID (No. 13)	Pass
Supplementary information:			

Other Enclosures

All Enclosures associated with this report are shown below.

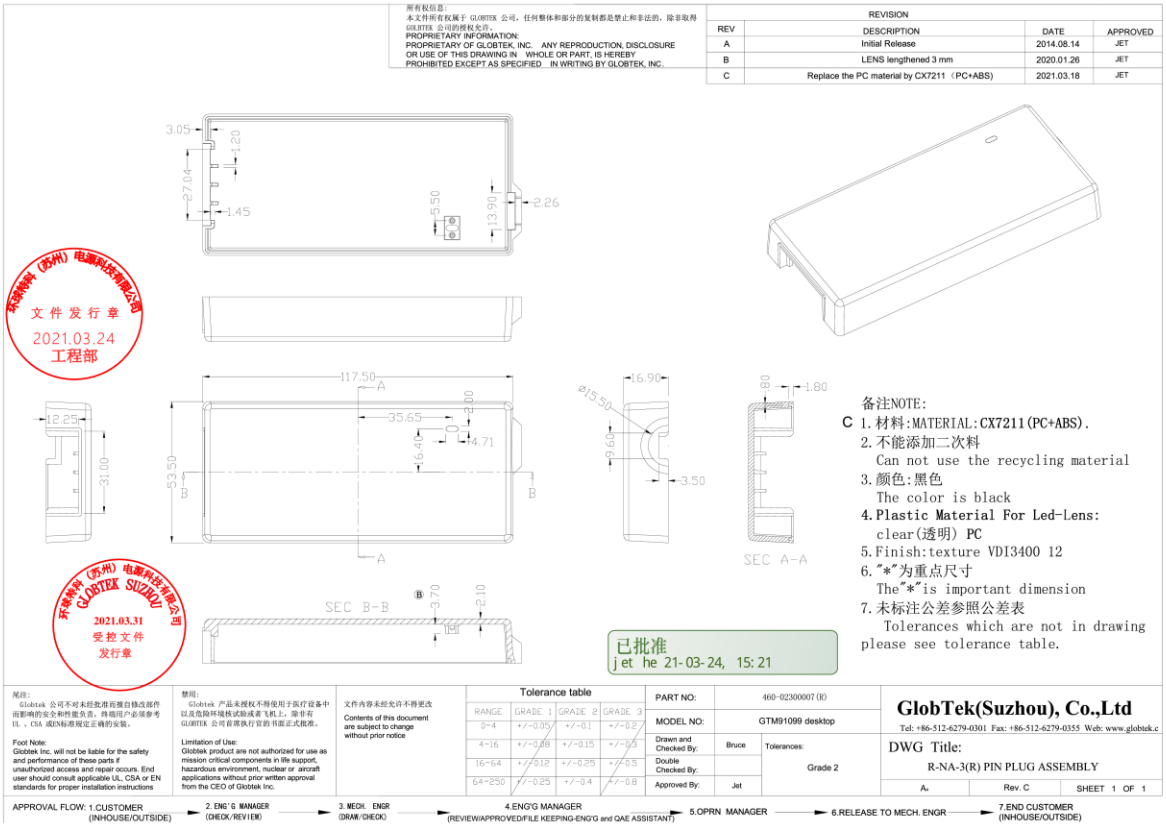
Enclosures

Supplement - (ID)	Description
Diagrams - (001)	001. Dimensional drawing for desktop models
Diagrams - (002)	002. Dimension drawing for hybrid desktop housing models
Diagrams - (003)	003. Dimension drawing for Encapsulated models
Diagrams - (004)	004. T1 type TF058 Specification
Diagrams - (005)	005. T1 type TF059 Specification
Diagrams - (006)	006. T1 type TF060 Specification
Diagrams - (007)	007. T1 type TF063 Specification
Diagrams - (008)	008. T1 type TF064 Specification
Diagrams - (009)	009. Insulation tape on HS1
Diagrams - (010)	010. HS1 Spec.
Diagrams - (011)	011. HS2 for desktop models
Diagrams - (012)	012. HS2 for Encapsulation models
Diagrams - (013)	013. Primary Cord guard (for desktop model)
Diagrams - (014)	014. Primary Cord guard (For Encapsulated model)
Diagrams - (015)	015. Secondary cord guard (for desktop model)
Diagrams - (016)	016. Secondary cord guard (for hybrid desktop model)
Diagrams - (017)	017. Secondary cord guard (for Encapsulated model)
Marking Label - (001)	Representative label_GTM96600-4005-TP3NA
Marking Label - (002)	Representative label_GTM96600-4005-TPNA
Marking Label - (003)	Representative label_GTM96600-6554-R3A
Miscellaneous - (001)	001. Model differences for class II medical power supply
Miscellaneous - (002)	002. Client declaration table -Class II
Photographs - (001)	001. hybrid desktop housing type overall view
Photographs - (002)	002. hybrid desktop housing type label side view
Photographs - (003)	003. hybrid desktop housing type label side view
Photographs - (004)	004. hybrid desktop housing type side view
Photographs - (005)	005. hybrid desktop housing type inside view
Photographs - (006)	006. hybrid desktop housing type inside view
Photographs - (007)	006a. hybrid desktop housing type inside view
Photographs - (008)	007. desktop type overall view
Photographs - (009)	007a. desktop type overall view
Photographs - (010)	008. desktop type label side view
Photographs - (011)	009. desktop type side view.jpg
Photographs - (012)	010. desktop type inside view

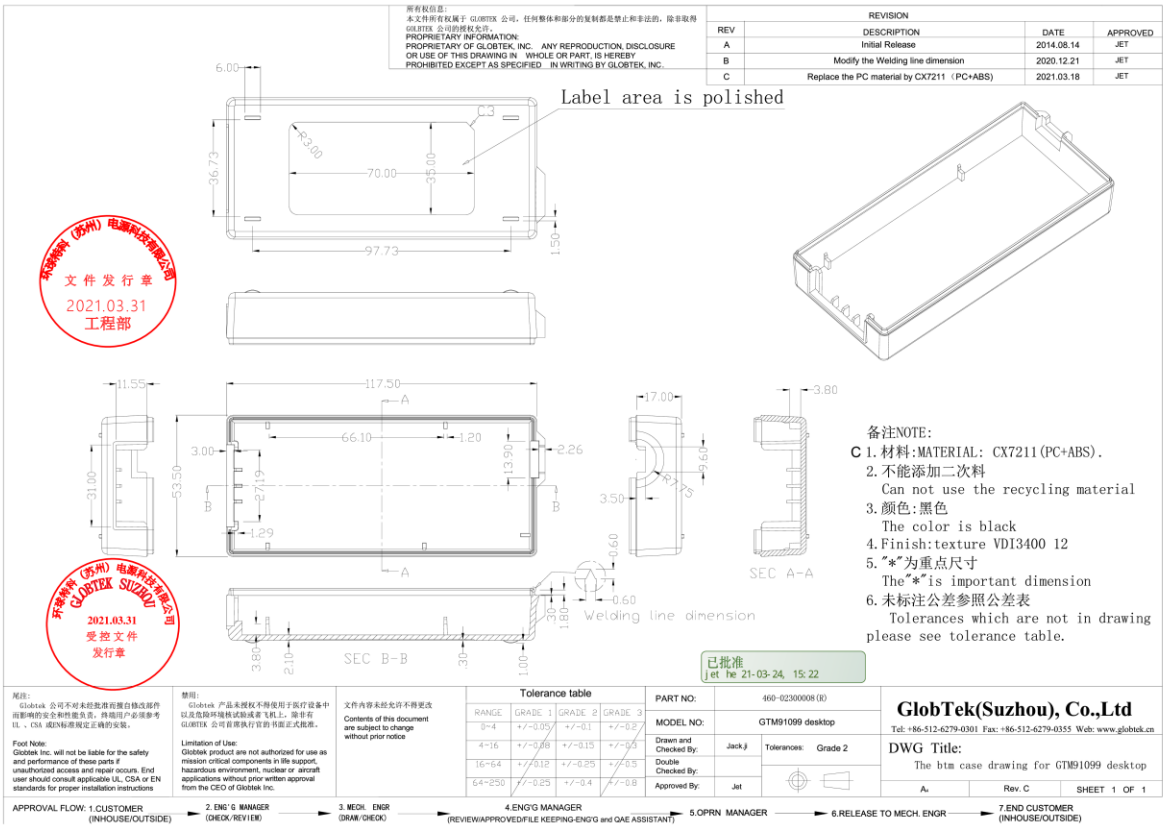
Photographs - (013)	011. desktop type inside view
Photographs - (014)	012. Encapsulated type overall view
Photographs - (015)	013. Encapsulated type label side view.jpg
Photographs - (016)	014. Encapsulated type inside view.jpg
Photographs - (017)	015. component side view
Photographs - (018)	016. pcb bottom view
Photographs - (019)	017. component side view
Photographs - (020)	017. HS1
Photographs - (021)	018. component side view (F2 insulation construction)
Photographs - (022)	018. HS1
Photographs - (023)	019. component side view (F3 insulation construction)
Photographs - (024)	019. component side view
Photographs - (025)	020. component side view (E2 insulation construction)
Photographs - (026)	020. component side view
Photographs - (027)	021. T1 upside view
Photographs - (028)	022. T1 bottom side view
Schematics + PWB - (001)	PCB layout version 1
Schematics + PWB - (002)	PCB layout version 2

Diagrams - (001) 001. Dimensional drawing for desktop models

Diagrams - (001) 001. Dimensional drawing for desktop models

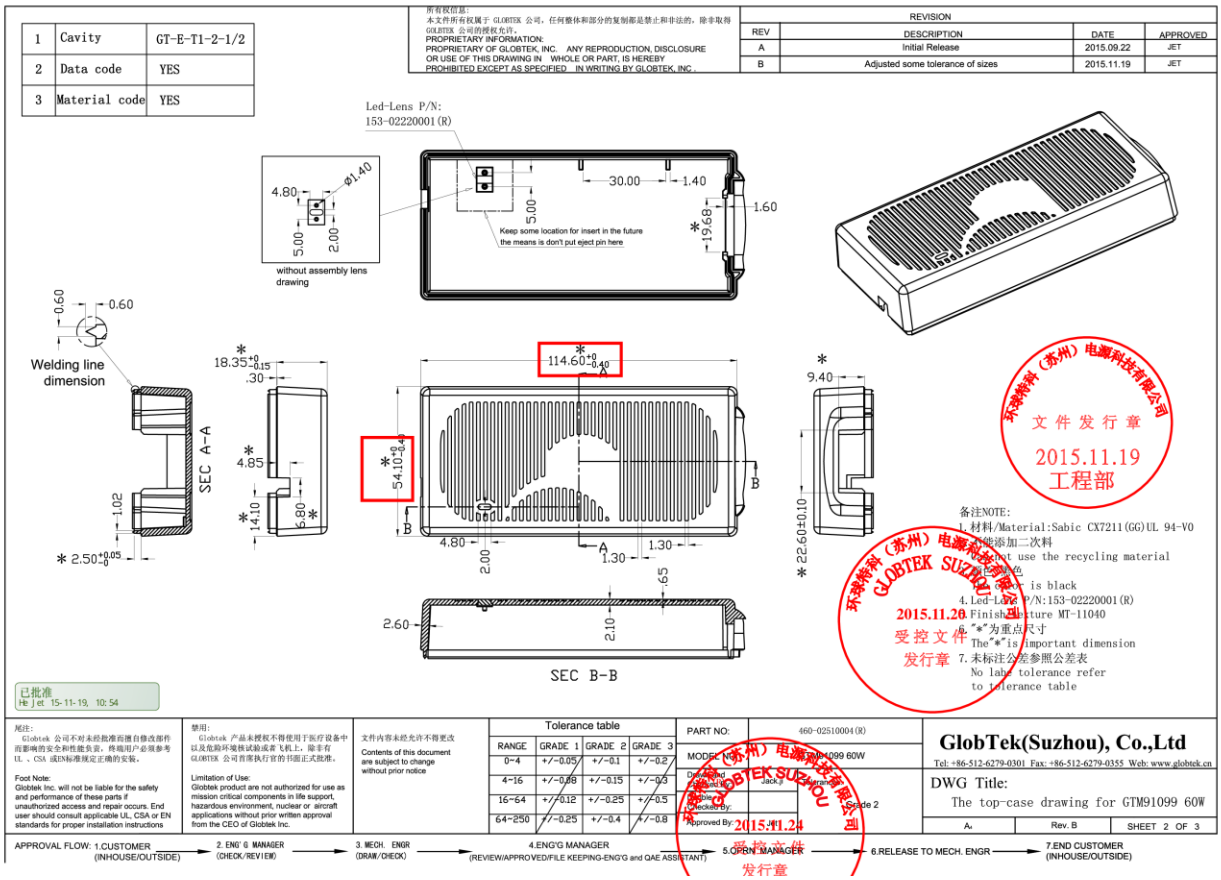


Diagrams - (001) 001. Dimensional drawing for desktop models

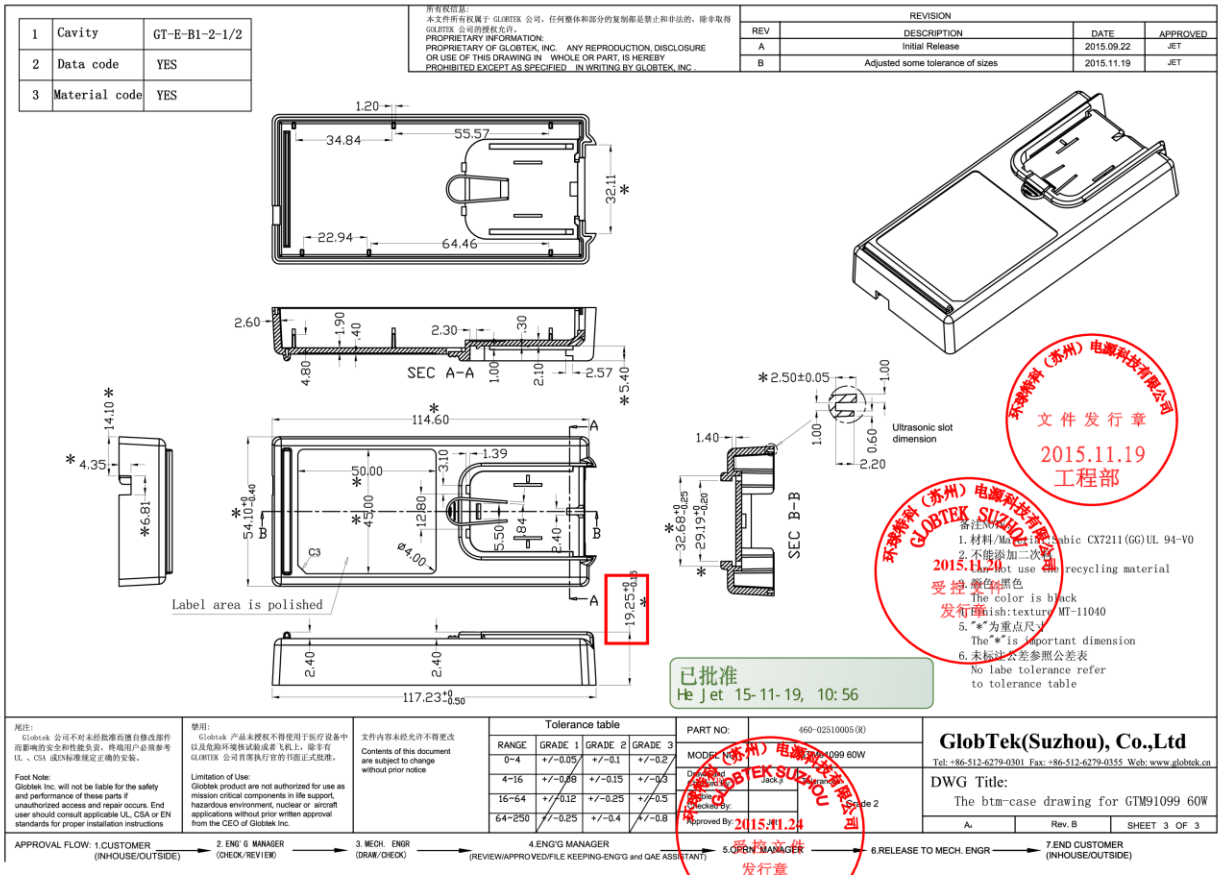


Diagrams - (002) 002. Dimension drawing for hybrid desktop housing models

Diagrams - (002) 002. Dimension drawing for hybrid desktop housing models

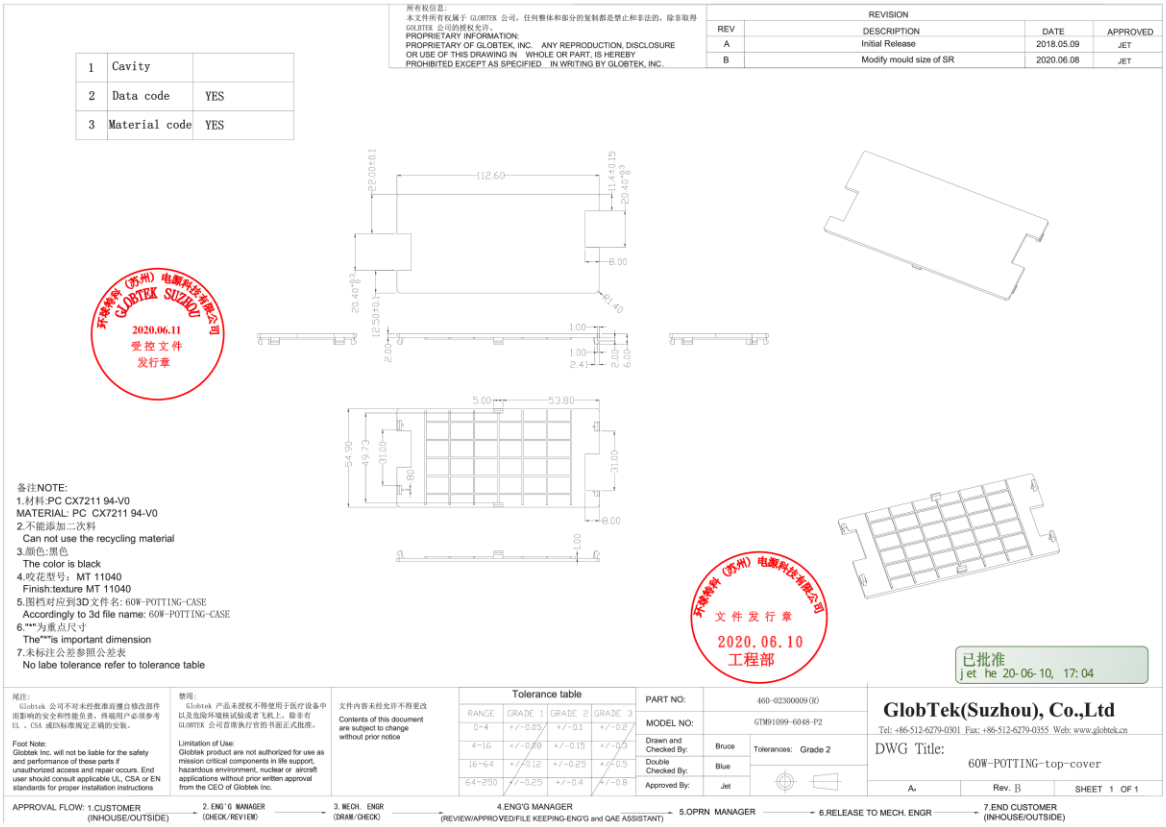


Diagrams - (002) 002. Dimension drawing for hybrid desktop housing models

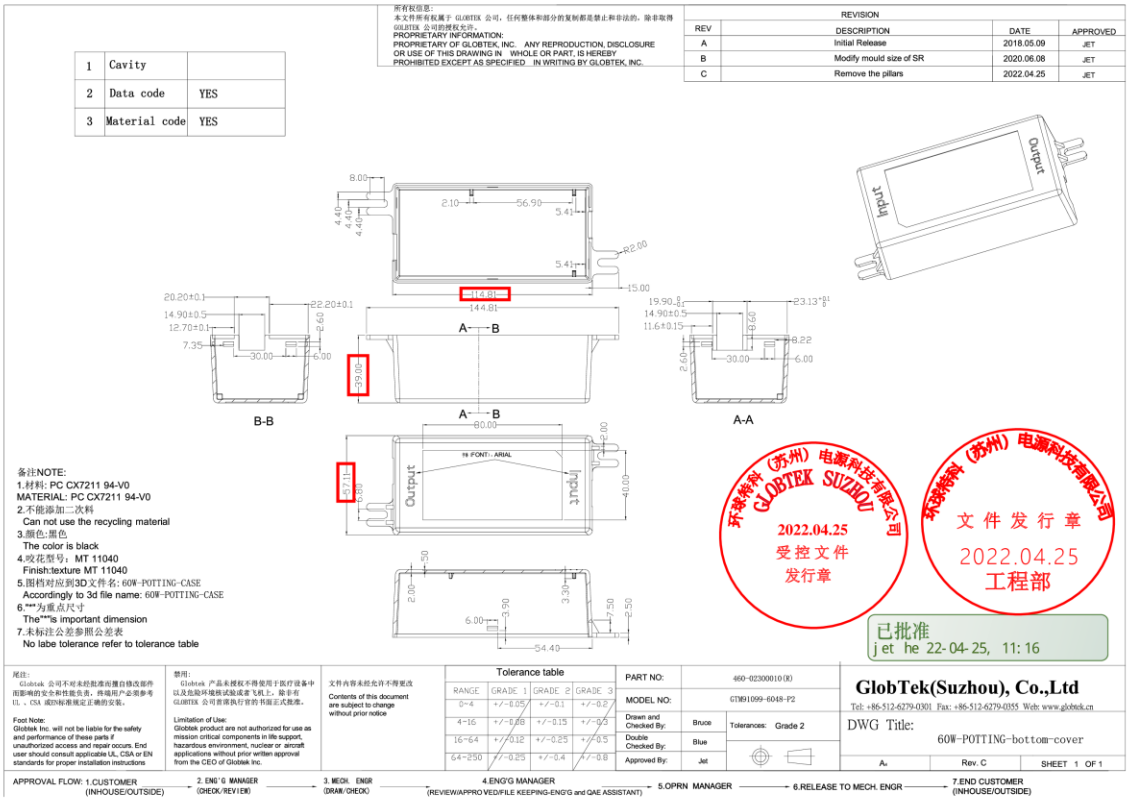


Diagrams - (003) 003. Dimension drawing for Encapsulated models

Diagrams - (003) 003. Dimension drawing for Encapsulated models



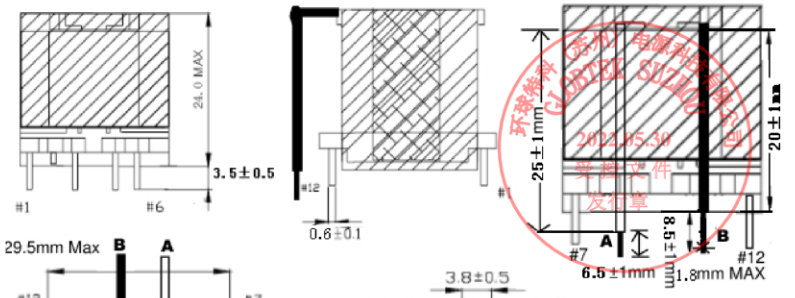
Diagrams - (003) 003. Dimension drawing for Encapsulated models



Diagrams - (004) 004. T1 type TF058 Specification

Diagrams - (004) 004. T1 type TF058 Specification

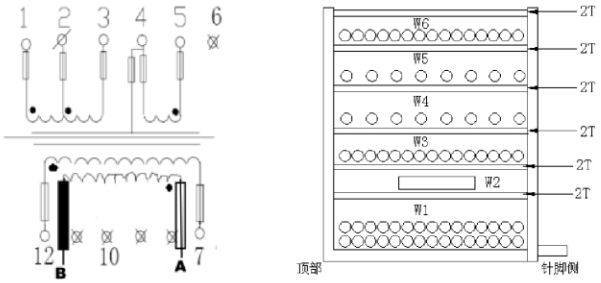
1. DIMENSION (UNIT : mm)





①PIN6,8,9,10,11 空脚。PIN2 剪去 2/3，不能超出骨架最底部（骨架挡板）
②飞线引出线直径焊锡之后≤1.8mm。
③A 套白色套管，从骨架顶部测量为 31.5mm±2,套管 25mm±1,引线焊锡 6.5mm±1mm。B 套黑色套管，从骨架顶部测量为 28.5mm±2,套管 20mm±1,引线焊锡 8.5mm±1mm。白色套管从侧面折向底部，黑色套管从顶部直接折向针脚侧，套管不超骨架挡墙板。.
④底部磁芯中柱贴一片 1350T-1 3M 胶带，然后用 30mm 宽 1350T-1 3M 胶带裹覆（参考上图）
⑤变压器顶部包裹胶带需超出 core 边缘 1.5mm。

2. SHCEMATIC：



WUXIHAOPUWEI ELECTRONICS CO.,LTD.			TITLE	UNIT	mm
DESIGN	CHECK	APPRO.	POWER XMFR		
			HPW SPEC NO	DATE	2022.05.20
			320-02986002	PAGE	3/5

Diagrams - (004) 004. T1 type TF058 Specification

3. ELECTRICAL CHARACTERISTICS

NO	ITEM	TERMINAL	SPECIFICATION	REMARKS
3-1	INDUCTANCE	1-3	440uH±10%	GainKaiTa3250 @1KHz,0.25Vrms
3-2	LEAK INDUCTANCE	1-3 路其他绕组	36uH MAX	内阻<100Ω
3-4	HI-POT TESTING	Pri-Sec	AC4.6KV/5mA/2S	CJ2670
		Pri-Core	AC2.0KV/5mA/2S	
		Sec-Core	AC 2.0KV/5mA/2S	

环球电气(苏州)有限公司 GLOBTEK SUZHOU 电源科技有限公司 2022.05.30 受控文件 发行章

4. WINDING SPEC

顺序 Order	PIN 脚 PIN No.	铜线 Copper wire	圈数 Turns	线槽 Slot	方向 Direction	备注 Remarks
W1	1---2	2UEW0.30*2mm Class B	25T			2LAYEAR
2turns W=9.5mm,T=0.025mm insulation tape						
W2	4	Coper foil 8mm*0.05(非自粘)	1.1T			Center
2turns W=9.5mm,T=0.025mm insulation tape						
W3	A---B	TRWB0.55*4mm	3T			1LAYEAR
2turns W=9.5mm,T=0.025mm insulation tape						
W4	12---7	TRWB0.20mm	7T		EVEN SPACING	
2turns W=9.5mm,T=0.025mm insulation tape						
W5	5---4	2UEW0.25*2mm Class B	9T		EVEN SPACING	
2turns W=9.5mm,T=0.025mm insulation tape						
W6	2---3	2UEW0.30*2 Class B	11T			1LAYEAR
2turns W=22mm,T=0.025mmOutside tape						
2turns W=11mm,T=0.025mm Corefixing tape						
2turns W=14mm,T=0.025mm Outsiden tape						

WUXI HAOPUWEI ELECTRONICS CO.,LTD.			TITLE	UNIT	mm
DESIGN	CHECK	APPRO.	POWER XMFR		
			HPW SPEC NO	DATE	2022.05.20
			320-02986002	PAGE	4/5

Diagrams - (004) 004. T1 type TF058 Specification

6. MATERIAL LIST.

NAME	SPEC	MANUFACTURER	SGS/CTI	UL	CLASS
BOBBIN	T375HF	CHANGCHUN	SGS: ETR21C00845	E59481	150℃
CORE. PQ2720	SP44	SANLIN	SGS:CANEC2206834102		
	M44	HAOBO	SGS:CANEC2200136208		
WIRE	2UEW	NINBO JINTIAN	SGS:SHAMLP2202874917	E227047	155℃
	TRWB	GREATLEOFLONINDUSTRIAL	SGS: ETR21A01543	E211989	130℃
TAPE	CT	YAHUA	SGS:CANEC2120251301	E165111	130℃
	1350T-1	3M	SGS:ETR21A03613	E17385	130℃
Varnish	T-4260(a)	TAIHU INSULATING MATERIAL	CTI:A2210494360101001E	E228349	130℃
TUBE	WF	WOER	CTI:A2210285449101008C	E203950	200℃

***DATA SHEET**

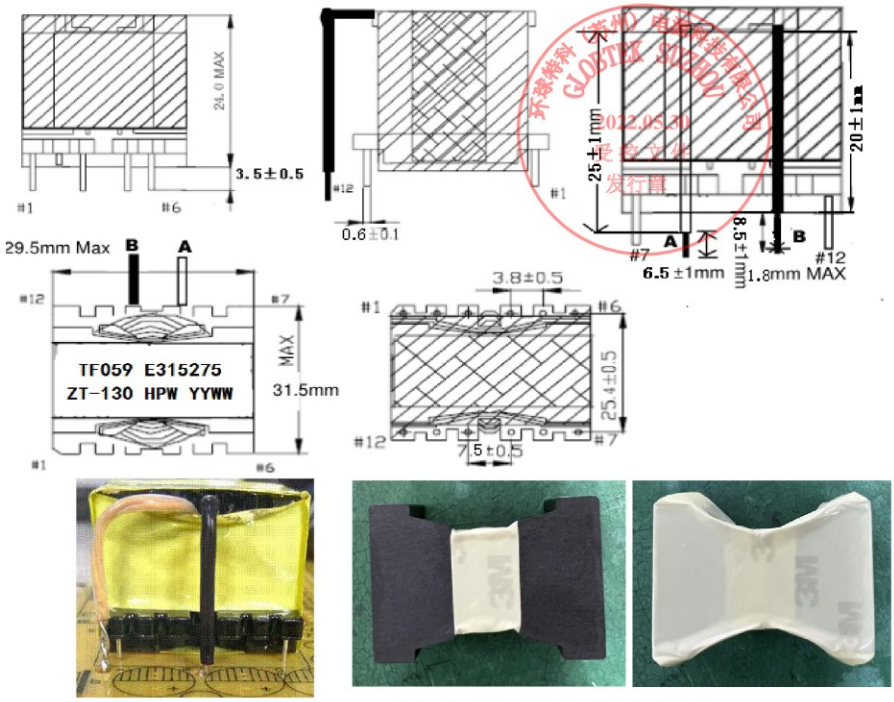
TESTING INST	GainKaiTa3250		TEMP/HUMIDITY		25℃/60℃	
QUANTITY	2EA		DATA OF MEAS		22.05.20	
ITEM		INDUCTANCE				
PIN NO	S.T.D	#1	#2	#3	#4	#5
L(1-3)	396uH-484uH	443	434			
Lk(1-3)	36uH MAX	18.7	18.6			
DIELECTRIC WITHSTANDING VOLTAGE						
		#1	#2	#3	#4	#5
Pri-Sec:AC 4.6KV/5mA/2S		OK	OK			
Pri-Core: AC2.0KV/5mA/2S		OK	OK			
Sec-Core: AC2.0KV/5mA/2S		OK	OK			

WUXI HAOPUWEI ELECTRONICS CO.,LTD.			TITLE	UNIT	mm
DESIGN	CHECK	APPRO.	POWER XMFR		
			HPW SPEC NO	DATE	2022.05.20
			320-02986002	PAGE	5/5

Diagrams - (005) 005. T1 type TF059 Specification

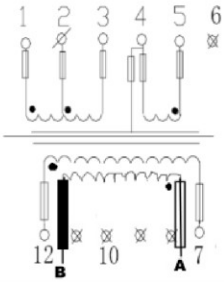
Diagrams - (005) 005. T1 type TF059 Specification

1. DIMENSION (UNIT : mm)



①PIN6,8,9,10,11 空脚。PIN2 剪去 2/3，不能超出骨架最底部（骨架挡板）
②飞线引出线直径焊锡之后≤1.8mm。
③A 套白色套管，从骨架顶部测量为 31.5mm±2,套管 25mm±1,引线焊锡 6.5mm±1mm。B 套黑色套管，从骨架顶部测量为 28.5mm±2,套管 20mm±1,引线焊锡 8.5mm±1mm。白色套管从侧面折向底部，黑色套管从顶部直接折向针脚侧，套管不超骨架挡墙板。
④变压器顶部包裹胶带需超出 core 边缘 1.5mm。
⑤底部磁芯中柱贴一片 1350T-1 3M 胶带，然后用 30mm 宽 1350T-1 3M 胶带裹覆（参考上图）

2. SHCEMATIC：



WUXIHAOPUWEI ELECTRONICS CO.,LTD.			TITLE	UNIT	mm
DESIGN	CHECK	APPRO.	POWER XMFR		
			HPW SPEC NO	DATE	2022.05.20
			320-02984402	PAGE	3/5

Diagrams - (005) 005. T1 type TF059 Specification

3. ELECTRICAL CHARACTERISTICS

NO	ITEM	TERMINAL	SPECIFICATION	REMARKS
3-1	INDUCTANCE	1-3	440uH±10%	GainKaiTa3250 @1KHz,0.25Vrms 内阻 100Ω
3-2	LEAK INDUCTANCE	1-3 路其他绕组	36uH MAX	
3-4	HI-POT TESTING	Pri-Sec	AC4.6KV/5mA/2S	CJ2670
		Pri-Core	AC2.0KV/5mA/2S	
		Sec-Core	AC 2.0KV/5mA/2S	

GLOBTEK SUZHOU 2022.05.30 受控文件 发行章

4. WINDING SPEC

顺序 Order	PIN 脚 PIN No.	铜线 Copper wire	圈数 Turns	线槽 Slot	方向 Direction	备注 Remarks
W1	1---2	2UEW0.30*2mm Class B	25T			2LAYEAR
2turns W=9.5mm,T=0.025mm insulation tape						
W2	4	Coper foil 8mm*0.05(非自粘)	1.1T			Center
2turns W=9.5mm,T=0.025mm insulation tape						
W3	A---B	TRWB0.55*4mm	4T			1LAYEAR
2turns W=9.5mm,T=0.025mm insulation tape						
W4	12---7	TRWB0.20mm	4T		EVEN SPACING	
2turns W=9.5mm,T=0.025mm insulation tape						
W5	5---4	2UEW0.25*2mm Class B	5T		EVEN SPACING	
2turns W=9.5mm,T=0.025mm insulation tape						
W6	2---3	2UEW0.30*2 Class B	11T			1LAYEAR
2turns W=22mm,T=0.025mmOutside tape						
2turns W=11mm,T=0.025mm Corefixing tape						
2turns W=14mm,T=0.025mm Outsiden tape						

WUXI HAOPUWEI ELECTRONICS CO.,LTD.			TITLE	UNIT	mm
DESIGN	CHECK	APPRO.	POWER XMFR		
			HPW SPEC NO	DATE	2022.05.20
			320-02984402	PAGE	4/5

Diagrams - (005) 005. T1 type TF059 Specification

6. MATERIAL LIST.

NAME	SPEC	MANUFACTURER	SGS/CTI	UL	CLASS
BOBBIN	T375HF	CHANGCHUN	SGS: ETR21C00845	E59481	150℃
CORE. PQ2720	SP44	SANLIN	SGS:CANEC2206834102		
	M44	HAOBO	SGS:CANEC2200136208		
WIRE	2UEW	NINBO JINTIAN	SGS:SHAMLP2202874917	E227047	155℃
	TRWB	GREATLEOFLONINDUSTRIAL CO LTD	SGS: ETR21A01543	E211989	130℃
TAPE	CT	YAHUA	SGS:CANEC2120251301	E165111	130℃
	1350T-1	3M	SGS:ETR21A03613	E17385	130℃
Varnish	T-4260(a)	TAIHU INSULATING MATERIAL	CTI:A2210494360101001E	E228349	130℃
TUBE	WF	WOER	CTI:A2210285449101008C	E203950	200℃

2022.05.30 受控文件

***DATA SHEET**

TESTING INST	GainKaiTa3250	TEMP/HUMIDITY	25℃/60℃
QUANTITY	2EA	DATA OF MEAS	22.05.20

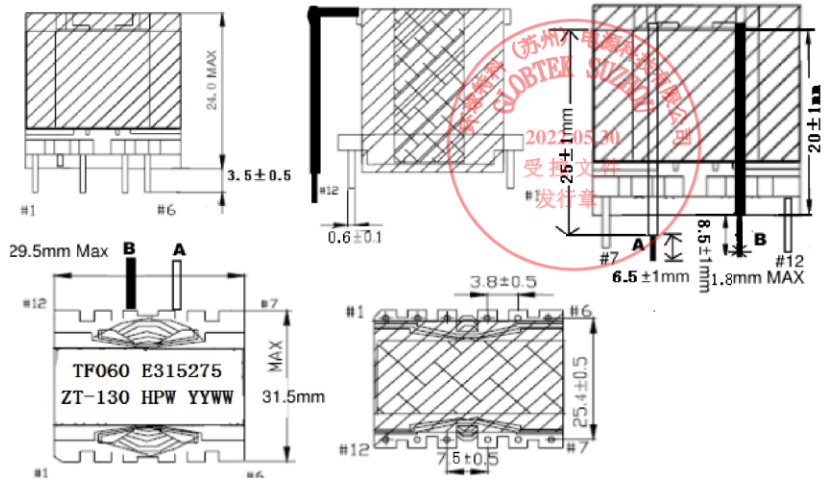
ITEM		INDUCTANCE				
PIN NO	S.T.D	#1	#2	#3	#4	#5
L(1-3)	396uH-484uH	428	455			
Lk(1-3)	36uH MAX	16	16.4			
DIELECTRIC WITHSTANDING VOLTAGE						
		#1	#2	#3	#4	#5
Pri-Sec:AC 4.6KV/5mA/2S		OK	OK			
Pri-Core: AC2.0KV/5mA/2S		OK	OK			
Sec-Core: AC 2.0KV/5mA/2S		OK	OK			

WUXI HAOPUWEI ELECTRONICS CO.,LTD.			TITLE	UNIT	mm
DESIGN	CHECK	APPRO.	POWER XMFR		
			HPW SPEC NO	DATE	2022.05.20
			320-02984402	PAGE	5/5

Diagrams - (006) 006. T1 type TF060 Specification

Diagrams - (006) 006. T1 type TF060 Specification

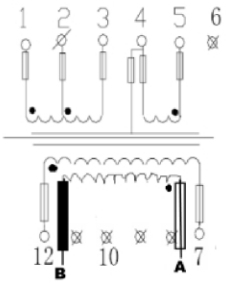
1. DIMENSION (UNIT : mm)





①PIN6,8,9,10,11 空脚。PIN2 剪去 2/3，不能超出骨架最底部（骨架挡板）
②飞线引出线直径焊锡之后≤1.8mm。
③A 套白色套管，从骨架顶部测量为 31.5mm±2,套管 25mm±1,引线焊锡 6.5mm±1mm。B 套黑色套管，从骨架顶部测量为 28.5mm±2,套管 20mm±1,引线焊锡 8.5mm±1mm。白色套管从侧面折向底部，黑色套管从顶部直接折向针脚侧，套管不超骨架挡墙板。
④铜箔长度为 40.5mm±0.5mm.
⑤变压器顶部包裹胶带需超出 core 边缘 1.5mm。
⑥底部磁芯中柱贴一片 1350T-1 3M 胶带，然后用 30mm 宽 1350T-1 3M 胶带裹覆（参考上图）

2. SHCEMATIC:



WUXIHAOPUWEI ELECTRONICS CO.,LTD.			TITLE	UNIT	mm
DESIGN	CHECK	APPRO.	POWER XMFR		
			HPW SPEC NO	DATE	2022.05.20
			320-02974402	PAGE	3/5

Diagrams - (006) 006. T1 type TF060 Specification

3. ELECTRICAL CHARACTERISTICS

NO	ITEM	TERMINAL	SPECIFICATION	REMARKS
3-1	INDUCTANCE	1-3	440uH±10%	GainKaiTa3250 @1KHz,0.25Vrms
3-2	LEAK INDUCTANCE	1-3 路其他绕组	36uH MAX	内阻<100Ω
3-4	HI-POT TESTING	Pri-Sec	AC4.6KV/5mA/2S	CJ2670
		Pri-Core	AC2.0KV/5mA/2S	
		Sec-Core	AC 2.0KV/5mA/2S	

环球电气(苏州)电源科技有限公司 GLOBTEK SUZHOU 2022.05.30 受控文件 发行章

4. WINDING SPEC

顺序 Order	PIN 脚 PIN No.	铜线 Copper wire	圈数 Turns	线槽 Slot	方向 Direction	备注 Remarks
W1	1---2	2UEW0.30*2mm Class B	25T			2LAYEAR
2turns W=9.5mm,T=0.025mm insulation tape						
W2	4	Coper foil 8mm*0.05(非自粘)	0.8T			Center
2turns W=9.5mm,T=0.025mm insulation tape						
W3	A---B	TRWB0.45*3mm	7T			2LAYEAR
2turns W=9.5mm,T=0.025mm insulation tape						
W4	5---4	2UEW0.25*2mm Class B	5T		EVEN SPACING	
2turns W=9.5mm,T=0.025mm insulation tape						
W5	2---3	2UEW0.30*2 Class B	11T			1LAYEAR
2turns W=22mm,T=0.025mmOutside tape						
2turns W=11mm,T=0.025mm Corefixing tape						
2turns W=14mm,T=0.025mm Outsiden tape						

WUXI HAOPUWEI ELECTRONICS CO.,LTD.			TITLE	UNIT	mm
DESIGN	CHECK	APPRO.	POWER XMFR		
			HPW SPEC NO	DATE	2022.05.20
			320-02974402	PAGE	4/5

Diagrams - (006) 006. T1 type TF060 Specification

6. MATERIAL LIST.

NAME	SPEC	MANUFACTURER	SGS/CTI	UL	CLASS
BOBBIN	T375HF	CHANGCHUN	SGS: ETR21C00845	E59481	150℃
CORE PQ2720	SP44	SANLIN	SGS:CANEC2206834102		
	M44	HAOBO	SGS:CANEC2200136208		
WIRE	2UEW	NINBO JINTIAN	SGS:SHAMLP2202874917	E227047	155℃
	TRWB	GREATLEOFLONINDUSTRIAL CO LTD	SGS: ETR21A01543	E211989	130℃
TAPE	CT	YAHUA	SGS:CANEC2120251301	E165111	130℃
	1350T-1	3M	SGS:ETR21A03613	E17385	130℃
Varnish	T-4260(a)	TAIHU INSULATING MATERIAL	CTI:A2210494360101001E	E228349	130℃
TUBE	WF	WOER	CTI:A2210285449101008C	E203950	200℃

***DATA SHEET**

TESTING INST	GainKaiTa3250	TEMP/HUMIDITY	25℃/60℃
QUANTITY	2EA	DATA OF MEAS	22.05.20

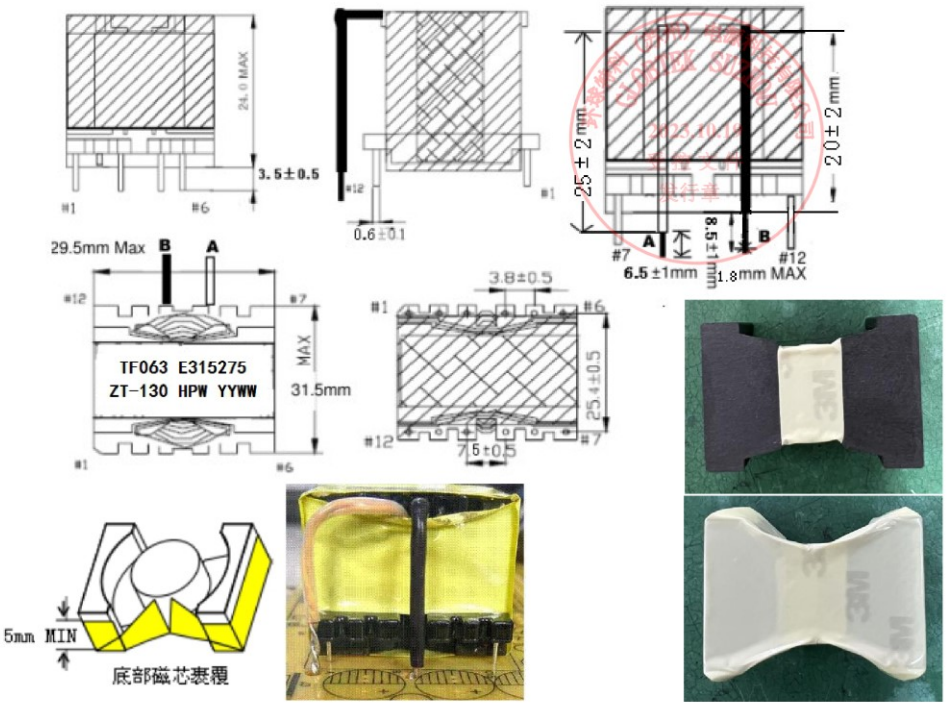
ITEM		INDUCTANCE				
PIN NO	S.T.D	#1	#2	#3	#4	#5
L(1-3)	396uH-484uH	428	430			
Lk(1-3)	36uH MAX	14.6	13.8			
DIELECTRIC WITHSTANDING VOLTAGE						
		#1	#2	#3	#4	#5
Pri-Sec:AC 4.6KV/5mA/2S		OK	OK			
Pri-Core: AC2.0KV/5mA/2S		OK	OK			
Sec-Core: AC2.0KV/5mA/2S		OK	OK			

WUXI HAOPUWEI ELECTRONICS CO.,LTD.			TITLE	UNIT	mm
DESIGN	CHECK	APPRO.	POWER XMFR		
			HPW SPEC NO	DATE	2022.05.20
			320-02974402	PAGE	5/5

Diagrams - (007) 007. T1 type TF063 Specification

Diagrams - (007) 007. T1 type TF063 Specification

1. DIMENSION (UNIT : mm)



①PIN6,8,9,10,11 空脚。PIN2 剪去2/3，不能超出骨架最底部（骨架挡板）。

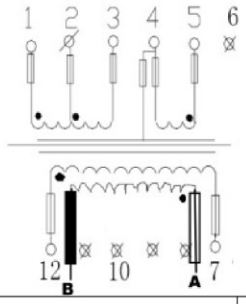
②飞线引出线直径焊锡之后≤1.8mm。

③A 套白色套管，从骨架顶部测量为 31.5mm±3,套管 25mm±2,引线焊锡 6.5mm±1mm。B 套黑色套管，从骨架顶部测量为 28.5mm±3,套管 20mm±1,引线焊锡 8.5mm±1mm。白色套管从侧面折向底部，黑色套管从顶部直接折向针脚侧，套管不超骨架挡墙板。

④底部磁芯中柱贴一片 1350T-1 3M 胶带，然后用 30mm 宽 1350T-1 3M 胶带裹覆（参考上图）

⑤变压器顶部包裹胶带需超出 core 边缘 1.5mm。

2. SHCEMATIC：



WUXIHAOPUWEI ELECTRONICS CO.,LTD.			TITLE	UNIT	mm
DESIGN	CHECK	APPRO.	POWER XMFR		
冯霞	王宇新	吴飞石	HPW SPEC NO	DATE	2023.09.28
			320-04944402	PAGE	3/5

Diagrams - (007) 007. T1 type TF063 Specification

3. ELECTRICAL CHARACTERISTICS

NO	ITEM	TERMINAL	SPECIFICATION	REMARKS
3-1	INDUCTANCE	1-3	440uH±10%	GainKaiTa3250 @1KHz,0.25Vrms 内阻 100Ω
3-2	LEAK INDUCTANCE	1-3 路其他绕组	36uH MAX	
3-4	HI-POT TESTING	Pri-Sec	AC4.6KV/5mA/2S	CJ2670
		Pri-Core	AC2.0KV/5mA/2S	
		Sec-Core	AC 2.0KV/5mA/2S	

2023.10.19 受控文件 发行章

4. WINDING SPEC

顺序 Order	PIN 脚 PIN No.	铜线 Copper wire	圈数 Turns	线槽 Slot	方向 Direction	备注 Remarks
W1	1---2	2UEW0.30*2mm Class B	25T			2LAYEAR
2turns W=9.5mm,T=0.025mm insulation tape						
W2	4	Coper foil 8mm*0.05(非自粘)	1.1T			Center
2turns W=9.5mm,T=0.025mm insulation tape						
W3	A---B	THL-F-TC 0.45*4mm	5T			2LAYEAR
2turns W=9.5mm,T=0.025mm insulation tape						
W4	12---7	THL-F-TC 0.20mm	4T		EVEN SPACING	
2turns W=9.5mm,T=0.025mm insulation tape						
W5	5---4	2UEW0.25*2mm Class B	5T		EVEN SPACING	
2turns W=9.5mm,T=0.025mm insulation tape						
W6	2---3	2UEW0.30*2 Class B	11T			1LAYEAR
2turns W=11mm,T=0.025mm Corefixing tape						
2turns W=22mm,T=0.025mmOutside tape						
2turns W=14mm,T=0.025mm Outsiden tape						

WUXI HAOPUWEI ELECTRONICS CO.,LTD.			TITLE	UNIT	mm
DESIGN	CHECK	APPRO.	POWER XMFR		
冯霞	王宇新	吴飞石	HPW SPEC NO	DATE	2023.09.28
			320-04944402	PAGE	4/5

Diagrams - (007) 007. T1 type TF063 Specification

6. MATERIAL LIST.

NAME	SPEC	MANUFACTURER	SGS/CTI	UL	CLASS
BOBBIN	T375HF	CHANGCHUN	SGS: ETR23205436	E59481	150℃
CORE PQ2720	SP44	SANLIN	SGS:SHAEC23004534601		
	M44	HAOBO	SGS:SZXEC2300020403		
WIRE	2UEW	NINBO JINTIAN	SGS: SHAPH23001684927	E227047	155℃
	THL-F-TC	HOI LUEN ELECTRICAL MFR CO LTD	CTI:A222048758510103	E257525	155℃
TAPE	CT	YAHUA	SGS:CANEC2222197401	E165111	130℃
	1350T-1	3M	SGS:ETR22A01980	E17385	130℃
Varnish	T-4260(a)	TAIHU INSULATING MATERIAL	CTI:A22303726991020O1E	E228349	130℃
TUBE	WF	WOER	CTI:CANEC2224268811	E203950	200℃

***DATA SHEET**

TESTING INST	GainKaiTa3250	TEMP/HUMIDITY	25℃/40%
QUANTITY	5EA	DATA OF MEAS	23.08.30

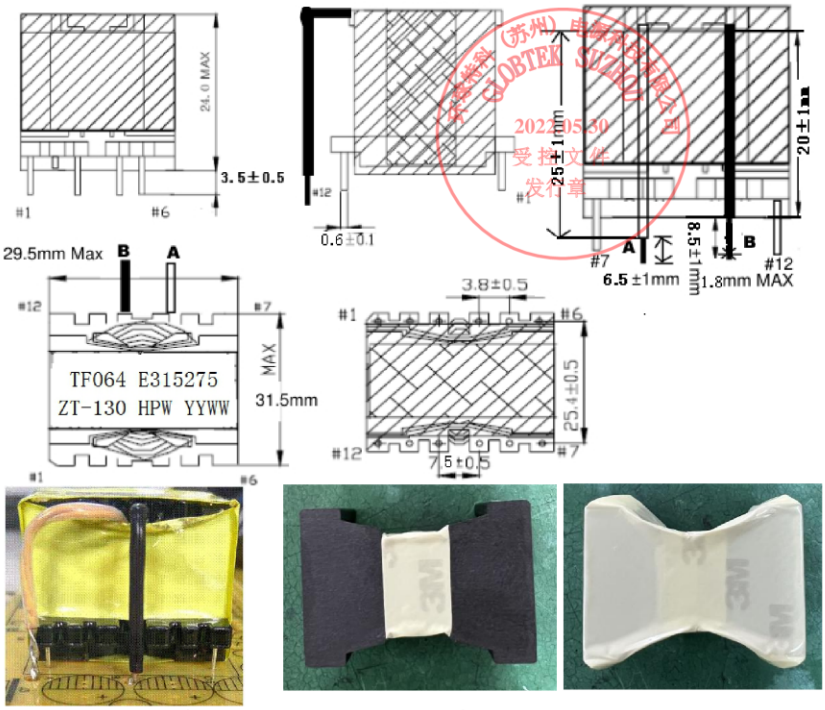
ITEM		INDUCTANCE				
PIN NO	S.T.D	#1	#2	#3	#4	#5
L(1-3)	396uH-484uH	446.3	446.4	446.1	445.1	445.5
Lk(1-3)	36uH MAX	20.45	16.47	17.1	16.78	16.1
DIELECTRIC WITHSTANDING VOLTAGE						
		#1	#2	#3	#4	#5
Pri-Sec:AC 4.6KV/5mA/2S		OK	OK	OK	OK	OK
Pri-Core: AC2.0KV/5mA/2S		OK	OK	OK	OK	OK
Sec-Core: AC 2.0KV/5mA/2S		OK	OK	OK	OK	OK

WUXI HAOPUWEI ELECTRONICS CO.,LTD.			TITLE	UNIT	mm
DESIGN	CHECK	APPRO.	POWER XMFR		
冯霞	王宇新	吴飞石	HPW SPEC NO	DATE	2023.09.28
			320-04944402	PAGE	5/5

Diagrams - (008) 008. T1 type TF064 Specification

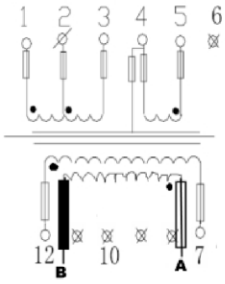
Diagrams - (008) 008. T1 type TF064 Specification

1. DIMENSION (UNIT : mm)



①PIN6,8,9,10,11 空脚。PIN2 剪去 2/3，不能超出骨架最底部（骨架挡板）
②飞线引出线直径焊锡之后≤1.8mm。
③A 套白色套管，从骨架顶部测量为 31.5mm±2,套管 25mm±1,引线焊锡 6.5mm±1mm。B 套黑色套管，从骨架顶部测量为 28.5mm±2,套管 20mm±1,引线焊锡 8.5mm±1mm。白色套管从侧面折向底部，黑色套管从顶部直接折向针脚侧，套管不超骨架挡墙板。
④铜箔长度为 45.5mm±0.5mm.
⑤变压器顶部包裹胶带需超出 core 边缘 1.5mm。
⑥底部磁芯中柱贴一片 1350T-1 3M 胶带，然后用 30mm 宽 1350T-1 3M 胶带裹覆（参考上图）

2. SHCEMATIC：



WUXIHAOPUWEI ELECTRONICS CO.,LTD.			TITLE	UNIT	mm
DESIGN	CHECK	APPRO.	POWER XMFR		
			HPW SPEC NO	DATE	2022.05.20
			320-02954402	PAGE	3/5

Diagrams - (008) 008. T1 type TF064 Specification

3. ELECTRICAL CHARACTERISTICS

NO	ITEM	TERMINAL	SPECIFICATION	REMARKS
3-1	INDUCTANCE	1-3	440uH±10%	GainKaiTa3250 @1KHz,0.25Vrms 内阻 100Ω
3-2	LEAK INDUCTANCE	1-3 路其他绕组	36uH MAX	
3-4	HI-POT TESTING	Pri-Sec	AC4.6KV/5mA/2S	CJ2670
		Pri-Core	AC2.0KV/5mA/2S	
		Sec-Core	AC2.0KV/5mA/2S	

GLOBTEK SUZHOU 2022.05.30 受控文件 发行章

4. WINDING SPEC

顺序 Order	PIN 脚 PIN No.	铜线 Copper wire	圈数 Turns	线槽 Slot	方向 Direction	备注 Remarks
W1	1---2	2UEW0.30*2mm Class B	25T			2LAYEAR
2turns W=9.5mm,T=0.025mm insulation tape						
W2	5	Coper foil 8mm*0.05(非自粘)	0.9T			Center
2turns W=9.5mm,T=0.025mm insulation tape						
W3	A---B	TRWB0.55*2mm	10T			2LAYEAR
2turns W=9.5mm,T=0.025mm insulation tape						
W4	5---4	2UEW0.25*2mm Class B	5T		EVEN SPACING	
2turns W=9.5mm,T=0.025mm insulation tape						
W5	2---3	2UEW0.30*2 Class B	11T			1LAYEAR
2turns W=22mm,T=0.025mmOutside tape						
2turns W=11mm,T=0.025mm Corefixing tape						
2turns W=14mm,T=0.025mm Outsiden tape						

WUXI HAOPUWEI ELECTRONICS CO.,LTD.			TITLE	UNIT	mm
DESIGN	CHECK	APPRO.	POWER XMFR		
			HPW SPEC NO	DATE	2022.05.20
			320-02954402	PAGE	4/5

Diagrams - (008) 008. T1 type TF064 Specification

6. MATERIAL LIST.

NAME	SPEC	MANUFACTURER	SGS/CTI	UL	CLASS
BOBBIN	T375HF	CHANGCHUN	SGS:ETR21C00845	E59481	150℃
CORE. PQ2720	SP44	SANLIN	SGS:CANEC2206834102		
	M44	HAOBO	SGS:CANEC2200136208		
WIRE	2UEW	NINBO JINTIAN	SGS:SHAMLP2202874917	E227047	155℃
	TRWB	GREATLEOFLONINDUSTRIAL CO LTD	SGS: ETR21A01543	E211989	130℃
TAPE	CT	YAHUA	SGS:CANEC2120251301	E165111	130℃
	1350T-1	3M	SGS:ETR21A03613	E17385	130℃
Varnish	T-4260(a)	TAIHU INSULATING MATERIAL	CTI:A2210494360101001E	E228349	130℃
TUBE	WF	WOER	CTI:A2210285449101008C	E203950	200℃

2022.05.30 受控文件

***DATA SHEET**

TESTING INST	GainKaiTa3250	TEMP/HUMIDITY	25℃/60℃
QUANTITY	2EA	DATA OF MEAS	22.05.20

ITEM		INDUCTANCE				
PIN NO	S.T.D	#1	#2	#3	#4	#5
L(1-3)	396uH-484uH	439	438			
Lk(1-3)	36uH MAX	10.4	10.6			
DIELECTRIC WITHSTANDING VOLTAGE						
		#1	#2	#3	#4	#5
Pri-Sec:AC 4.6KV/5mA/2S		OK	OK			
Pri-Core: AC2.0KV/5mA/2S		OK	OK			
Sec-Core: AC2.0KV/5mA/2S		OK	OK			

WUXI HAOPUWEI ELECTRONICS CO.,LTD.			TITLE	UNIT	mm
DESIGN	CHECK	APPRO.	POWER XMFR		
			HPW SPEC NO	DATE	2022.05.20
			320-02954402	PAGE	5/5

Diagrams - (009) 009. Insulation tape on HS1

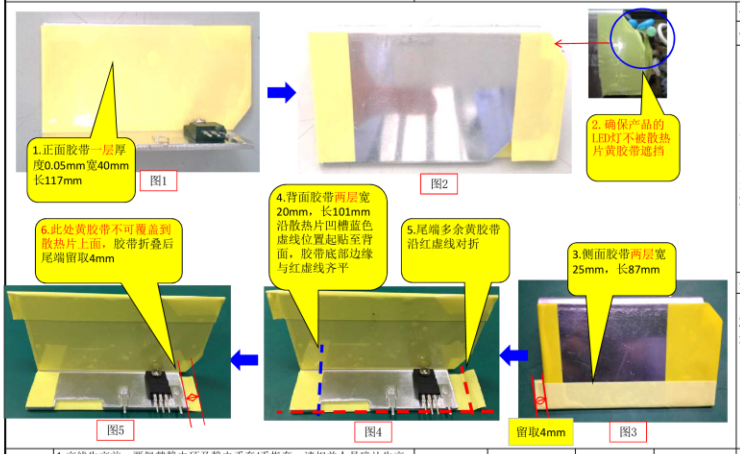
Diagrams - (009) 009. Insulation tape on HS1

GlobTek® (Suzhou) Co., Ltd
医疗、资讯、车载、特种电源

环球特科（苏州）电源科技有限公司

作业指导书
Standard Operating Procedure

机种：	GTM96600	
P/N：	xxxxxxxxxxxxx	
文件编号：	PIE-WS-5278-R1	
发行日期：	2022/5/6	
版本：	标准工时：	页码：
00-01	s/件	1



作业内容：加工线—15. HS1贴胶带

作业步骤：

1. 加工
1）. 如图1、2:对准散热片上边缘贴一层厚度0.05mm宽40mm长117mm的黄胶带；将胶带贴至散热片背面；沿斜线位置将黄胶带剪去,剪去后确保散热片依然被黄胶带包裹.散热片本体不可裸露.
2）. 如图3:调整自动胶带机，裁切两层宽25mm，长87mm的胶带，贴至散热片上，外侧留取4mm.
3）. 如图4、5:裁切两层宽20mm，长101mm黄胶带沿散热片凹槽蓝色虚线位置起贴至背面，胶带底部边缘与红虚线齐平,结尾端多余黄胶带沿红虚线对折,尾端黄胶带不可覆盖到散热片上面.
2. 确认OK后，进行批量加工.

作业注意事项：
1.胶布需贴平，不能有褶皱.
2.黄胶带需粘贴牢固，不可翘起，脱落.
3.图4处尾端黄胶带不可覆盖到散热片上面.

开线准备事项	治工具	名称	静电环	自动胶带机		制表	核准	QC
1.产线生产前，要佩戴静电环及静电手套/手指套，请相关人员确认生产设备参数并做好设备点检记录表及保养记录表. 2.各产线（加工、插件、半成品、成品）生产前作业注意事项： 根据SPEC及BOM核对上线物料，确认OK后按照SOP进行生产作业. 3.生产时如有异常；及时反馈QC、线长、组长、工程师、主管确认OK后，方可进行生产作业.		型号	EB-713					
		数量	1个	1台		吴晓丽		
		备注						

材料栏

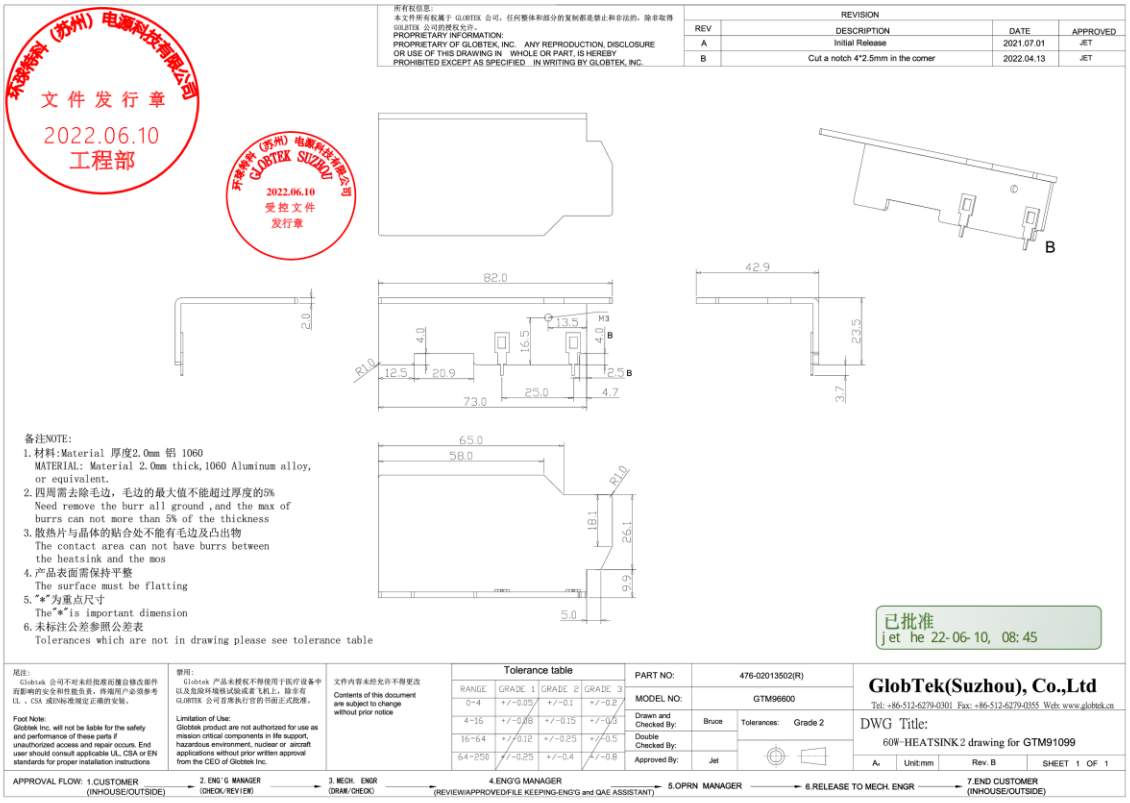
顺序	位置	名称	料号	规格	用量	极性
1	HS1	散热片	OSP-476-02013502®	散热片(Heatsink1) L型（42.9*23.5）×R2 铝片 厚2.0mm FOR GTM91099 DESKTOP VERSION	1	
2			476-02013502®	散热片(Heatsink1) L型（42.9*23.5）×R2 铝片 厚2.0mm FOR GTM91099 DESKTOP VERSION	0	
3	FOR HS1	黄胶带	MRO-00002251	H0.05mm*W40mm		
4			681-02502500®	H0.025mm*W25mm		
5			681-20025000®	H0.025mm*W20mm*L66M YELLOW		

变更事项记录

版本	日期	变更内容
00-01	2022/5/9	晶体外侧散热片增加2层黄胶带

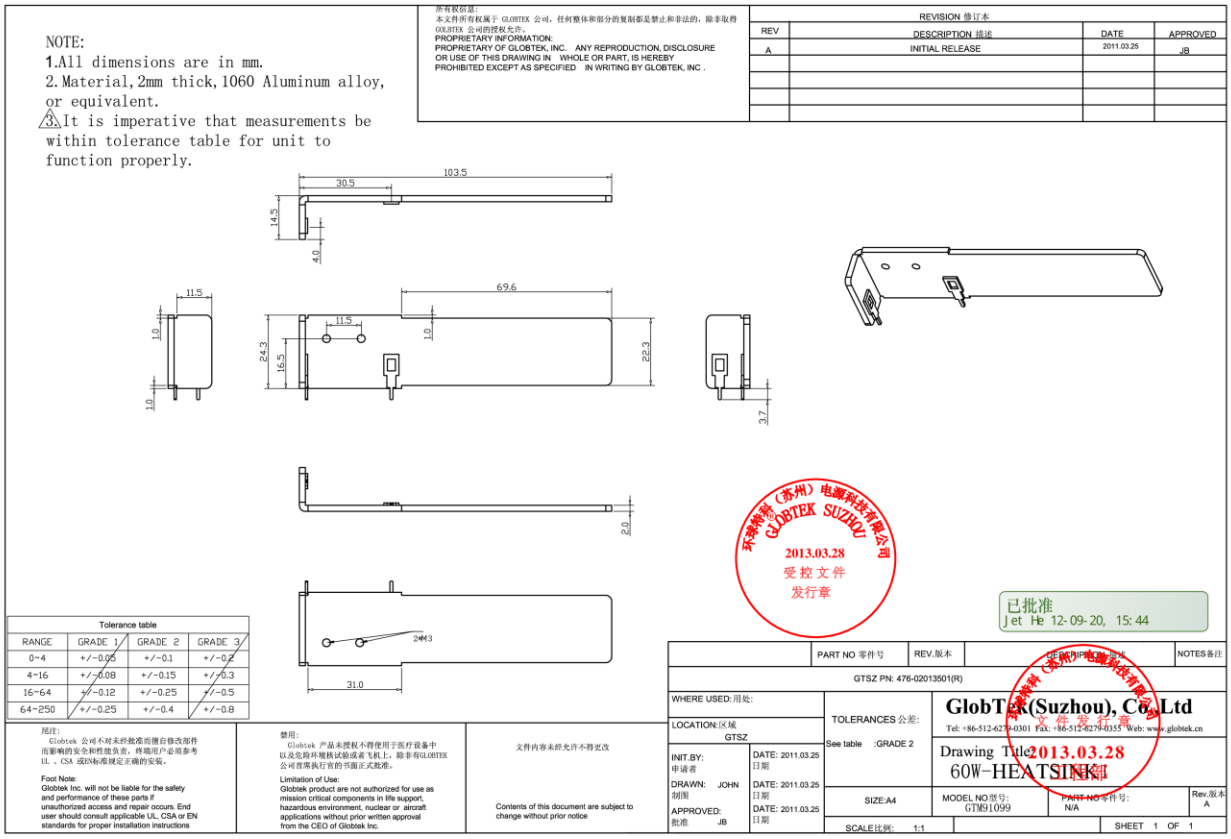
Diagrams - (010) 010. HS1 Spec.

Diagrams - (010) 010. HS1 Spec.



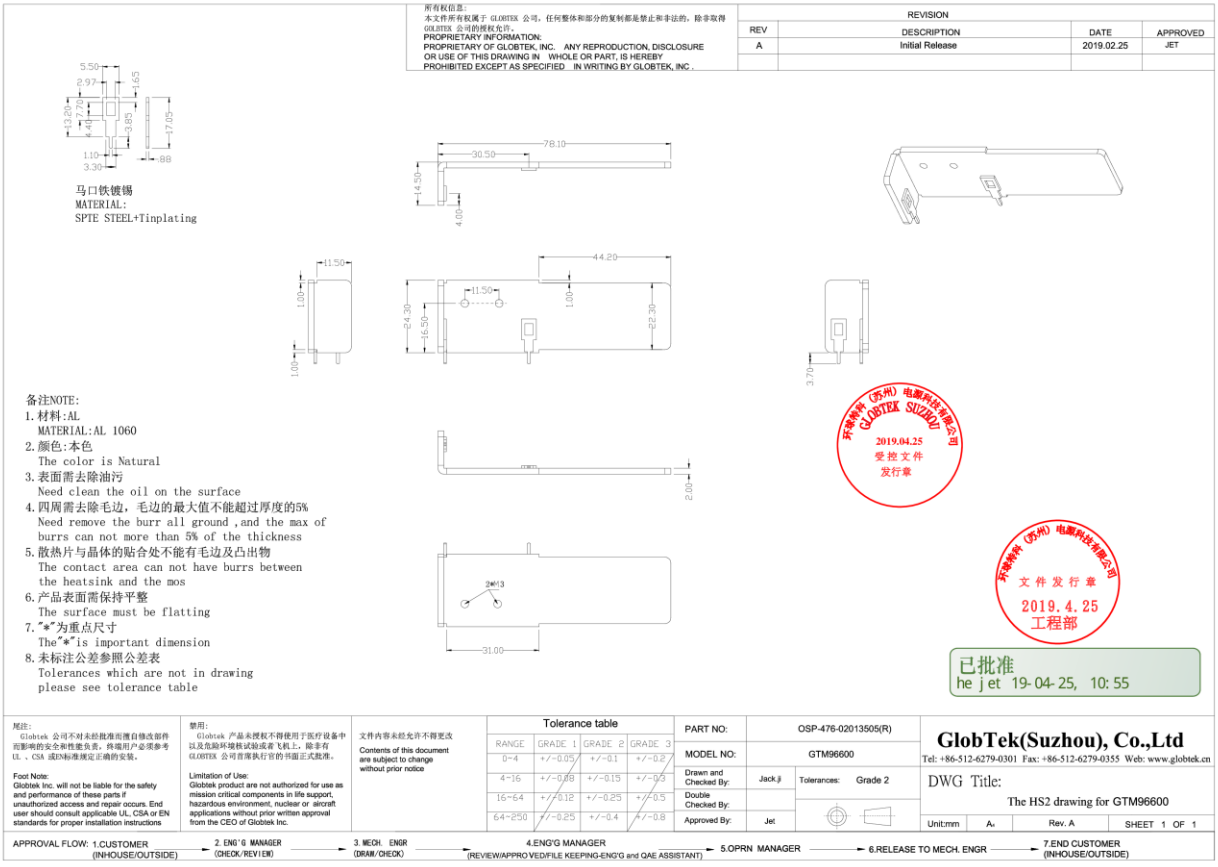
Diagrams - (011) 011. HS2 for desktop models

Diagrams - (011) 011. HS2 for desktop models



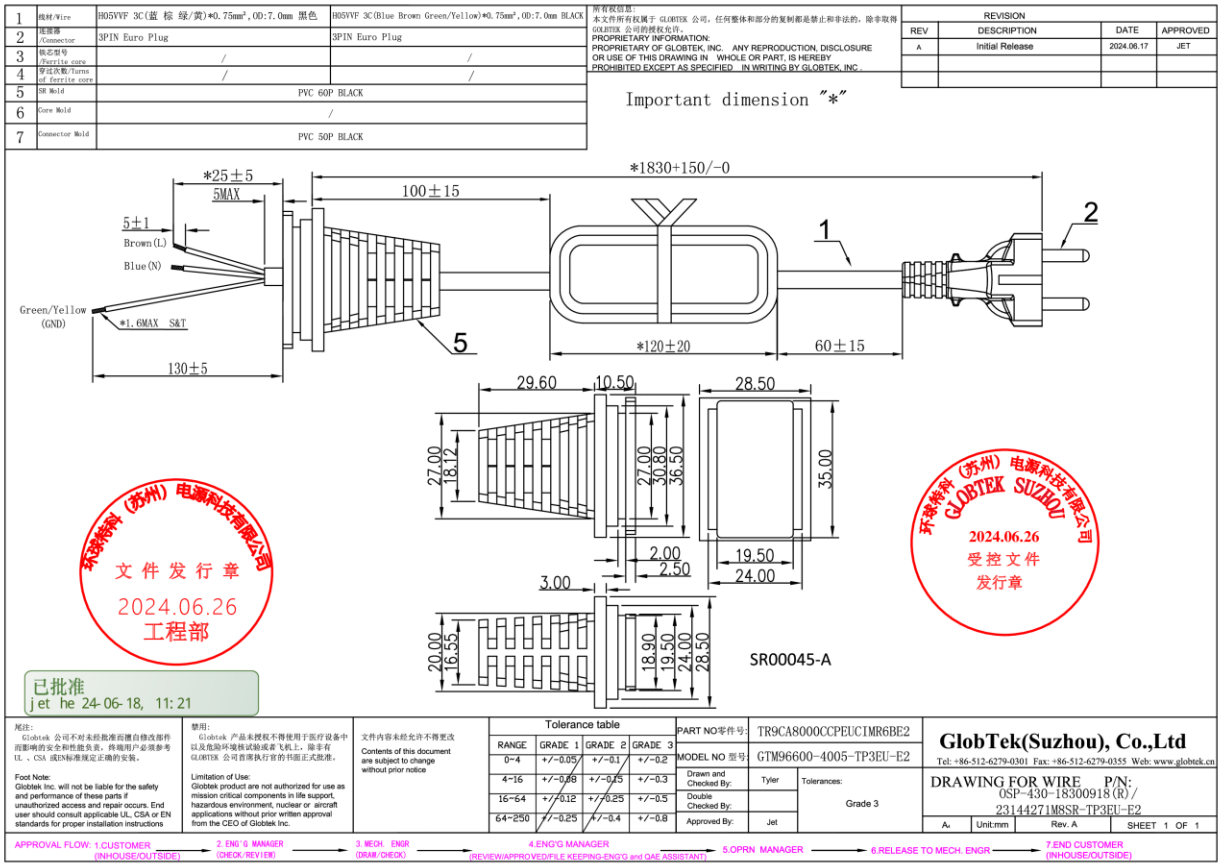
Diagrams - (012) 012. HS2 for Encapsulation models

Diagrams - (012) 012. HS2 for Encapsulation models



Diagrams - (013) 013. Primary Cord guard (for desktop model)

Diagrams - (013) 013. Primary Cord guard (for desktop model)



1	线材/Wire	H05VVF 3C(蓝 棕 绿/黄)*0.75mm²,OD:7.0mm 黑色	H05VVF 3C(Blue Brown Green/Yellow)*0.75mm²,OD:7.0mm BLACK
2	连接器 /Connector	3PIN Euro Plug	3PIN Euro Plug
3	格芯型号 /Ferrite core	/	/
4	穿过次数/Turns of ferrite core	/	/
5	SR Mold	PVC 6OP BLACK	
6	Core Mold	/	
7	Connector Mold	PVC 5OP BLACK	

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REVISION			
REV	DESCRIPTION	DATE	APPROVED
A	Initial Release	2024.06.17	JET

环球特种（苏州）电源科技有限公司 文件发行章 2024.06.26 工程部

环球特种（苏州）电源科技有限公司 GLOBTEK SUZHOU 2024.06.26 受控文件 发行章

已批准 jet he 24-06-18, 11:21

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Tolerance table

RANGE	GRADE 1	GRADE 2	GRADE 3
0~4	+/-0.05	+/-0.1	+/-0.2
4~16	+/-0.08	+/-0.15	+/-0.3
16~64	+/-0.12	+/-0.25	+/-0.5
64~250	+/-0.25	+/-0.4	+/-0.8

PART NO零件号:	TR9CA8000CCPEUCIMR6BE2
MODEL NO 型号:	GTM96600-4005-TP3EU-E2
Drawn and Checked By:	Tyler
Double Checked By:	
Approved By:	Jet
Tolerances:	Grade 3

GlobTek(Suzhou), Co.,Ltd
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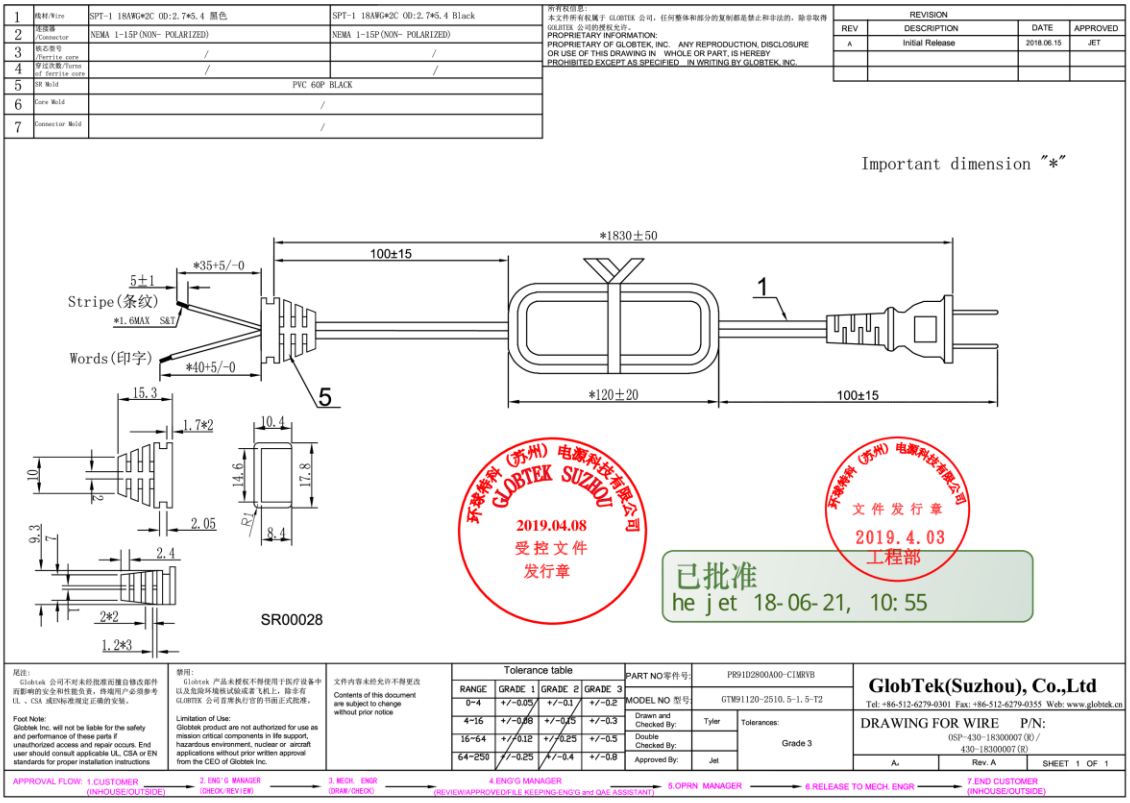
DRAWING FOR WIRE P/N: OSP-430-18300918(R)/ 23144271M8SR-TP3EU-E2

A.	Unit:mm	Rev. A	SHEET 1 OF 1

APPROVAL FLOW: 1.CUSTOMER (INHOUSE/OUTSIDE) → 2. ENG'G MANAGER (CHECK/REVIEW) → 3. MECH. ENGR (DRAW/CHECK) → 4.ENG'G MANAGER (REVIEW/APPROVED/FILE KEEPING-ENG'G and QAE ASSISTANT) → 5.OPRN MANAGER → 6.RELEASE TO MECH. ENGR → 7.END CUSTOMER (INHOUSE/OUTSIDE)

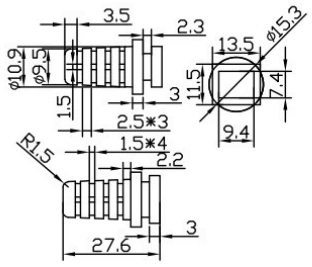
Diagrams - (014) 014. Primary Cord guard (For Encapsulated model)

Diagrams - (014) 014. Primary Cord guard (For Encapsulated model)



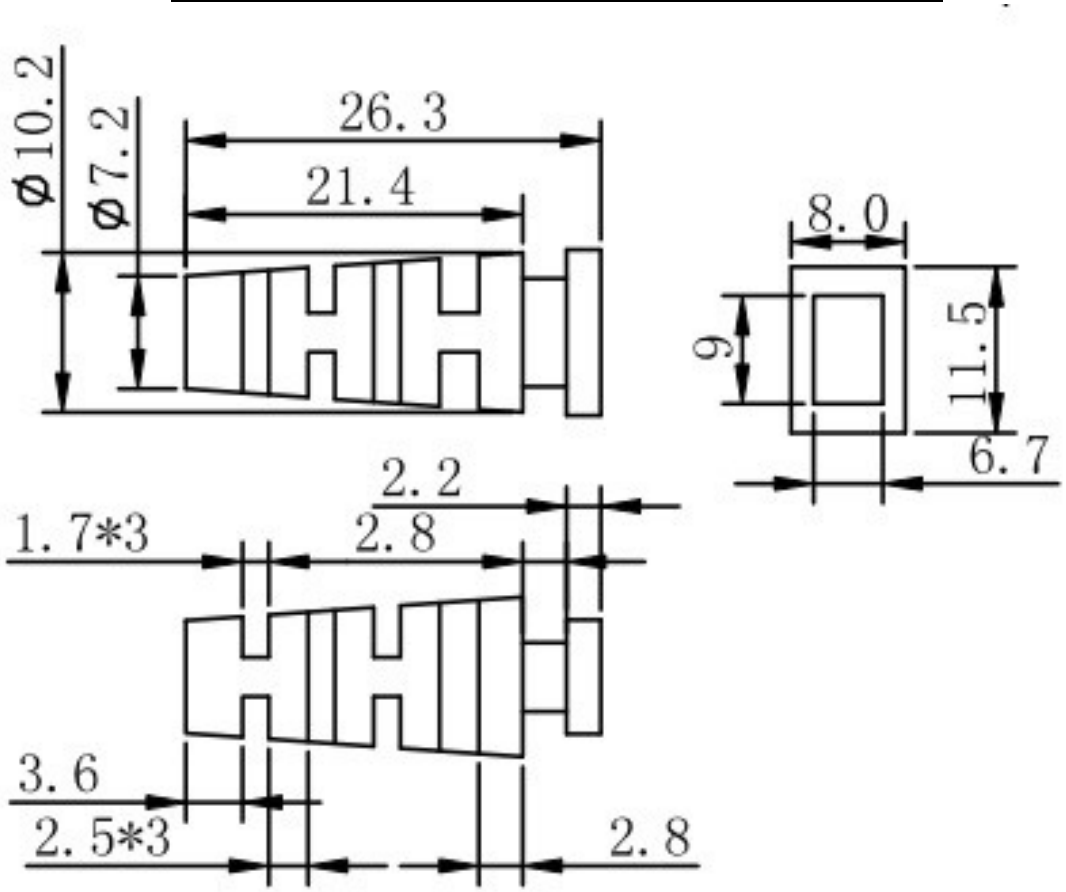
Diagrams - (015) 015. Secondary cord guard (for desktop model)

Diagrams - (015) 015. Secondary cord guard (for desktop model)



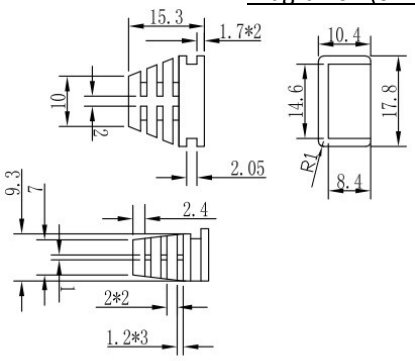
Diagrams - (016) 016. Secondary cord guard (for hybrid desktop model)

Diagrams - (016) 016. Secondary cord guard (for hybrid desktop model)



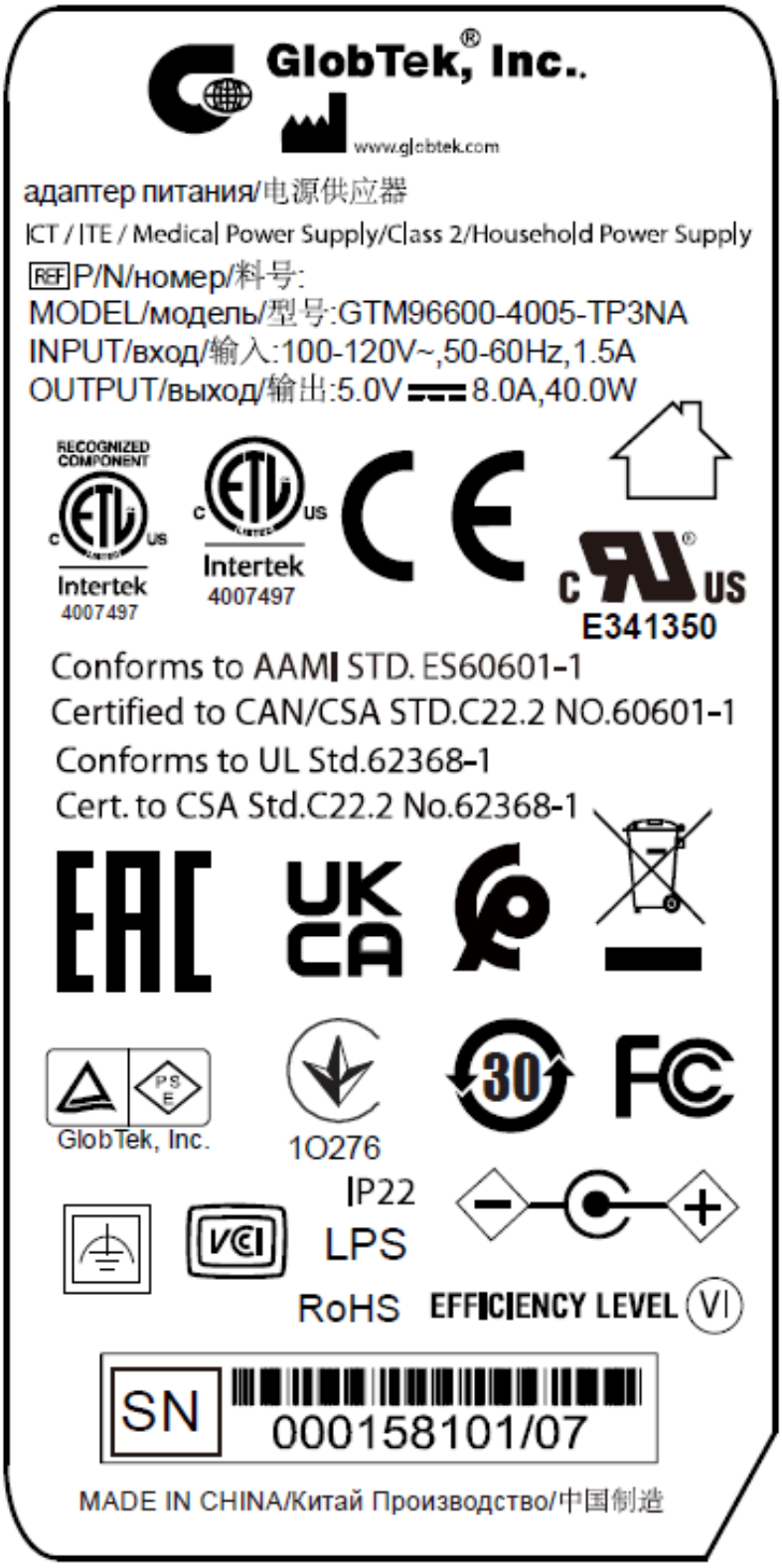
Diagrams - (017) 017. Secondary cord guard (for Encapsulated model)

Diagrams - (017) 017. Secondary cord guard (for Encapsulated model)



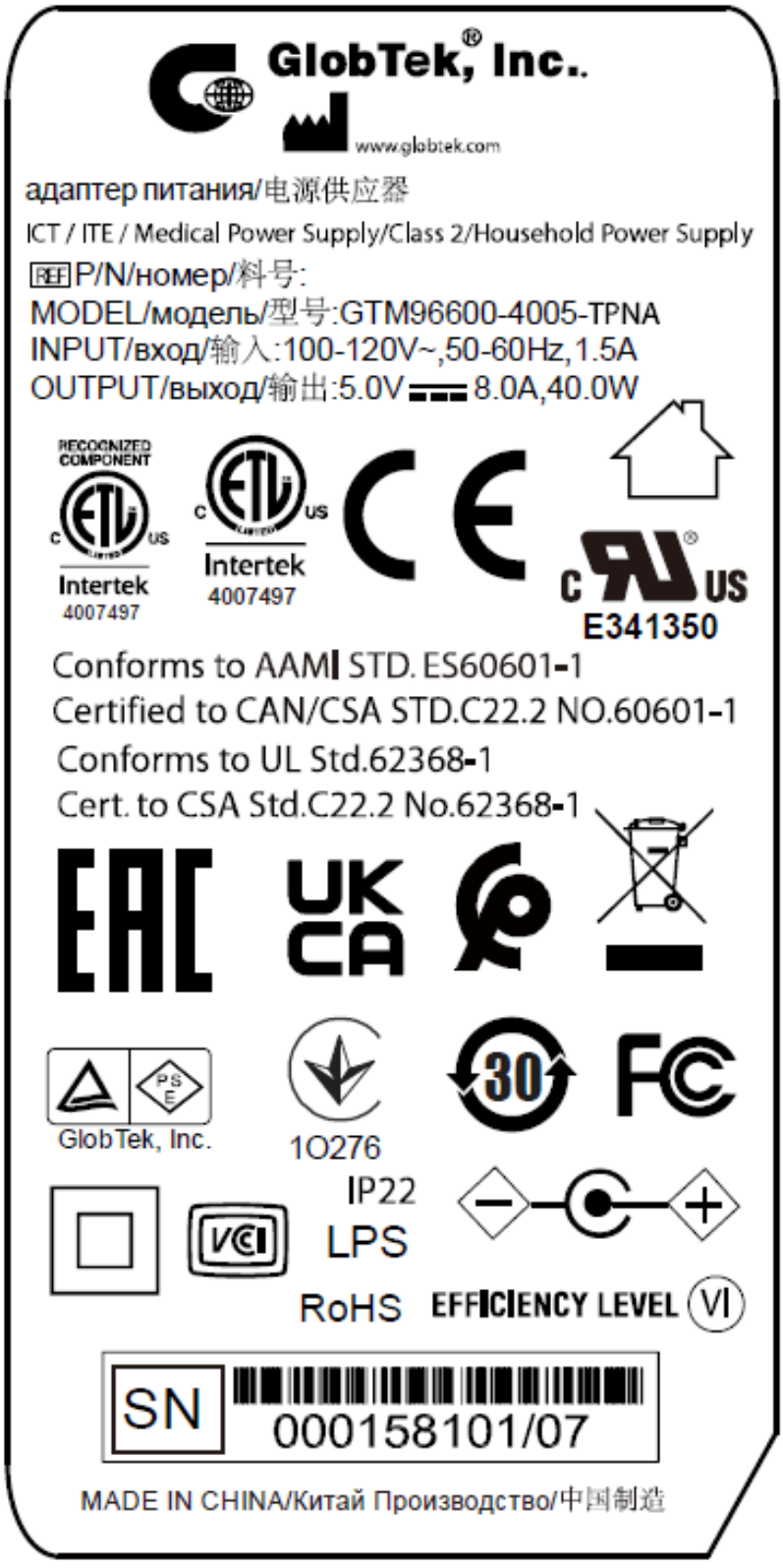
Marking Label - (001) Representative label_GTM96600-4005-TP3NA

Marking Label - (001) Representative label_GTM96600-4005-TP3NA



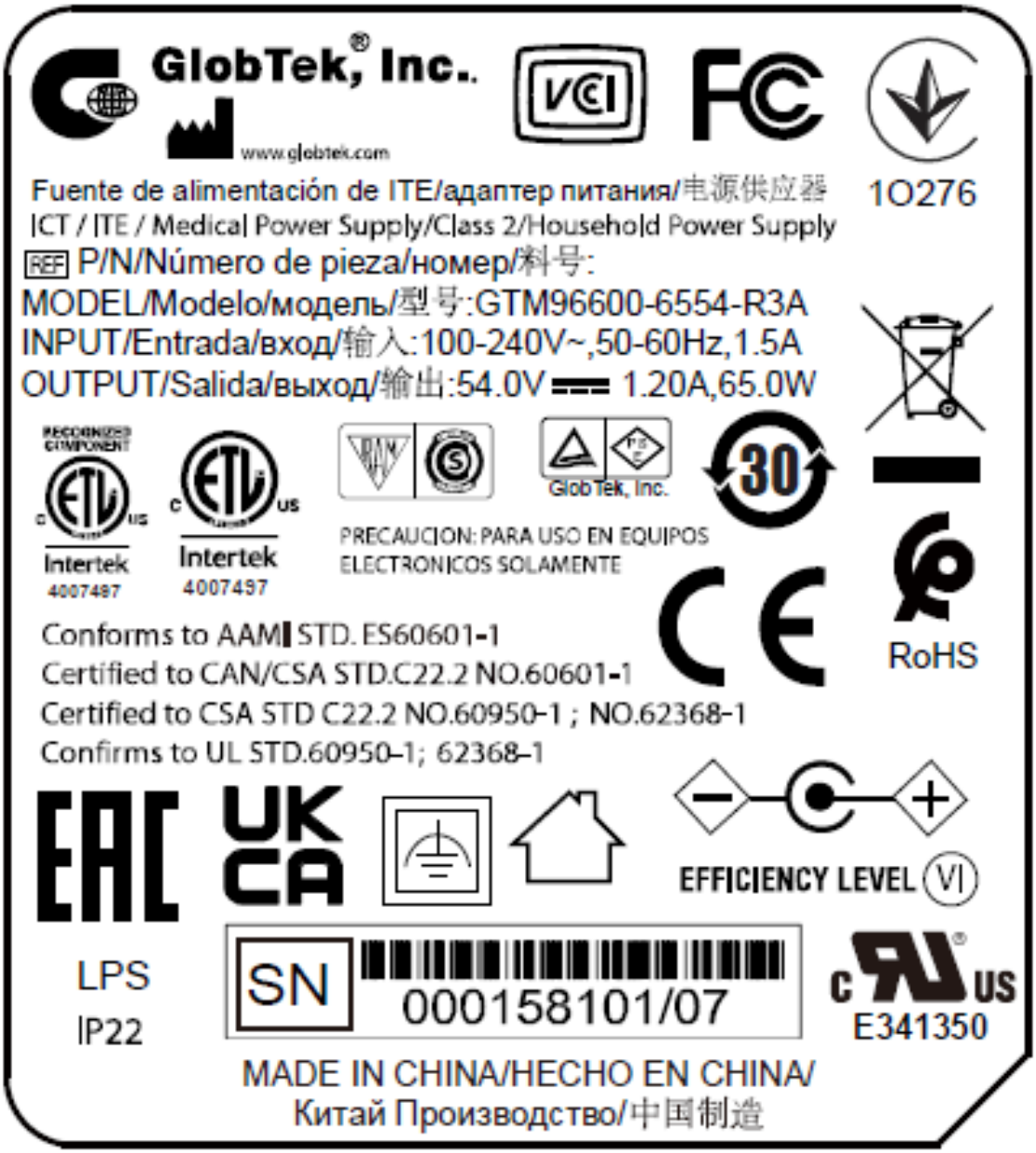
Marking Label - (002) Representative label_GTM96600-4005-TPNA

Marking Label - (002) Representative label_GTM96600-4005-TPNA



Marking Label - (003) Representative label_GTM96600-6554-R3A

Marking Label - (003) Representative label_GTM96600-6554-R3A

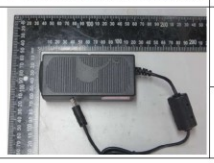


Miscellaneous - (001) 001. Model differences for class II medical power supply

Miscellaneous - (001) 001. Model differences for class II medical power supply

Model	Output Voltage	Max. output current	Max. output power	Transformer
GT*96600-**-T2/T2A/T3/T3A/T2L/T2AL/T3L/T3AL/R2/R3A/P2/P3/TP/TP3/TW/TW3*.	5-8.7VDC	8A	40W	TF058
GT*96600-**-T2/T2A/T3/T3A/T2L/T2AL/T3L/T3AL/R2/R3A/P2/P3/TP/TP3/TW/TW3*.	6.8-11VDC	6A	60W	TF058,TF059
GT*96600-**-T2/T2A/T3/T3A/T2L/T2AL/T3L/T3AL/R2/R3A/P2/P3/TP/TP3/TW/TW3*.	11.1-54VDC	5.42A	65W	TF059,TF063,TF060,TF064,TF061

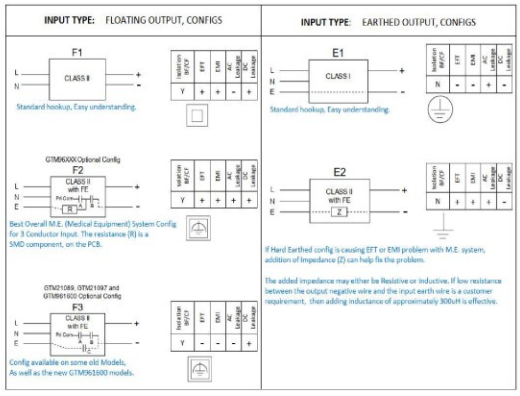
Note: Input rating 100-120Vac is for models with TP NA standard, 100-240Vac is for other models.

Model	SCH &PCB layout	Enclosure	Input Mode	ISOLATION DIAGRAMS
GT*96600-**-T2*	The same (see the tabel 1 as below)		AC inlet C8	F1
GT*96600-**-T2A*			AC inlet C18	F1
GT*96600-**-T3*			AC inlet C14	E2/F2/F3
GT*96600-**-T3A*			AC inlet C6	
GT*96600-**-T2L*			AC inlet C8	F1
GT*96600-**-T2AL*			AC inlet C18	
GT*96600-**-T3L*			AC inlet C14	E2/F2/F3
GT*96600-**-T3AL*			AC inlet C6	
GT*96600-**-TP*			power supply cord with plug 	F1
GT*96600-**-TP3*				E2/F2/F3
GT*96600-**-TW*			input wire without plug 	F1
GT*96600-**-TW3*				E2/F2/F3
GT*96600-**-P2*			input wire as the above two lines	F1
GT*96600-**-P3*				E2/F2/F3
GT*96600-**-R2*			AC inlet C8	F1
GT*96600-**-R3A*			AC inlet C6	E2/F2/F3

Tabel 1

Item	SCH	Layout	
PCB	1. with rectifying circuit	Versions 1 with C22 E33 CY2 reserved part(for F1/F2/F3)	Versions 2 with R32 reserved part (for F1/E2/F2)
	2. without rectifying circuit		

ISOLATION CONSTRUCTION



Note: E1 insulation construction is for class I medical power supply, here is for reference only.

Miscellaneous - (002) 002. Client declaration table -Class II

Miscellaneous - (002) 002. Client declaration table -Class II

For component without Risk Management Process, please declare the intended use and function of your product.

Clause for IEC60601-1, 3rd.	Intended use	Client declaration
Product information	Medical power supply	GT*96600-**-** The 1st "*" part can be 'M' or '-' or 'H' for market identification and not related to safety. The 2nd "*" denotes the rated output wattage designation, which can be "01" to "65", with interval of 1. The 3rd"*" denote the standard rated output voltage designation, which can be "05" to "54" or "5.0" to "54.0" in 0.1V increments. The 4th"*" can be "T2', "T2A", "T3", " T3A", "T2L", "T2AL", "T3L", " T3AL", "R2", "R3A", "P2", "P3", "TP", "TP3", "TW", "TW3", "T2" means desktop class II with C8 AC inlet, "T2A" means desktop class II with C18 AC inlet, "T3" means desktop class II with functional earth with C14 AC inlet "T3A" means desktop class II with functional earth with C6 AC inlet, "T2L" means desktop class II with C8 AC inlet and housing with a DC jack, "T2AL" means desktop class II with C18 AC inlet and housing with a DC jack, "T3L" means desktop class II with functional earth with C14 AC inlet and housing with a DC jack,

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Revision Date: 2011-05-23

Miscellaneous - (002) 002. Client declaration table -Class II

		"T3AL" means desktop class II with functional earth with C6 AC inlet and housing with a DC jack, "R2" means hybrid desktop housing class II with C8 AC inlet, "R3A" means hybrid desktop housing class II with functional earth with C6 AC inlet, "P2" means Encapsulated class II, "P3" means Encapsulated class II with functional earth, "TP" means desktop class II with power supply cord with plug, "TP3" means desktop class II with functional earth with power supply cord with plug, "TW" means desktop class II with input wire without plug, "TW3" means desktop class II with functional earth with input wire without plug The last * denote any six characters = 0-9 or A-Z or ()[] or – or blank for marketing purposes.
	Model difference	All modes in their respective series are identical to each other except for model name, output rating, the secondary winding of the transformer (T1), input AC inlet and case size （117.5 by 53.5 by 34.2mm for desktop model, 114.6 by 54.1 by 36.6mm for hybrid desktop housing, 114.81 by 57.11 by 39mm for Encapsulated model） and a few non-critical components that used to adjust the output.

Issue Date: 2011-05-11
Revision Date: 2011-05-23

Miscellaneous - (002) 002. Client declaration table -Class II

		When the model is F3 insulation diagram, the Bridge Y-Capacitors is Max. 1500 pF. There are two types of PCB Layout. PCB layout version 1 is for F1/F2/F3 insulation diagram with C22 R33 CY3 reserved part. PCB layout version 2 is for F1/E2/F2 insulation diagram with R32 reserved part. Desktop models have a copper foil and mylar on the Bottom Case. Hybrid desktop models have a mylar on the Bottom Case. Input rating 100-120Vac is for TP/TP3 models with NA standard plug, 100-240Vac is for other models.
	Input rating	100-240 Vac or 100-120 Vac (for TP/TP3 models with NA standard plug) _50-60_ Hz -1.5A
	Phase	Single
	Output rating/ output loading	5-54VDC, Max. 65W
	Output circuits are NOT intended for direct patient connection (Type B, BF or CF)	☒ Not intended ☐ Intended: _____ (circuit/output identity #_____)

Issue Date: 2011-05-11
Revision Date: 2011-05-23

Miscellaneous - (002) 002. Client declaration table -Class II

	Applied Part	☐ Type B ☐ Type BF ☐ Type CF ☒ To be determined in the end-product evaluation
	Mode of operation	☒ Continuous ☐ Duty Cycle: _____
	Maximum Operating temperature Tma	_Maximum 40_ degree C
	Maximum normal load	(Refer to "**Output rating/ output loading**" for details of the above) A
	Weight	_Maximum 0.35_ kg
	Dimension	117,50*53,50*34,20
	Accessories and detachable parts	☐ Part: _____ ☒ To be determined in the end-product evaluation
	Options include	☒ None ☐ _____
5.7 Humidity preconditioning treatment	Relative Humidity?	_93_ %RH
	Temperature?	30_ degree C
	Recommend Period for Humidity preconditioning treatment?	_48_ hrs (≥48hrs)
8.9 CREEPAGE DISTANCES and AIR CLEARANCES	Provides MOPP or MOOP isolation?	☒ MOOP ☒ MOPP
	Altitude?	_5000_ m
	Pollution Degree?	☐ 1 ☒ 2 ☐ 3

Issue Date: 2011-05-11
Revision Date: 2011-05-23

Miscellaneous - (002) 002. Client declaration table -Class II

<table>
<tr><td></td><td></td><td>☐ 4</td></tr>
<tr><td></td><td>Material group (CTI)?
Table 9—Material group classification<table><tr><th>Material group</th><th>Comparative tracking index (CTI)</th></tr><tr><td>I</td><td>600 ≤ CTI</td></tr><tr><td>II</td><td>400 ≤ CTI < 600</td></tr><tr><td>IIIa</td><td>175 ≤ CTI < 400</td></tr><tr><td>IIIb</td><td>100 ≤ CTI < 175</td></tr></table></td><td>☐ I
☐ II
☐ IIIa
☒ IIIb</td></tr>
<tr><td></td><td>Overvoltage category?</td><td>☐ I
☒ II
☐ III
☐ IV</td></tr>
<tr><td>11 Protection against excessive temperatures and other HAZARDS</td><td>Table 23: External surfaces of ME EQUIPMENT that are likely to be touched for a time “t”
Table 23—Allowable maximum temperatures for ME EQUIPMENT parts that are likely to be touched<table><tr><th colspan="2" rowspan="2">ME EQUIPMENT and its parts</th><th colspan="3">Maximum temperature [a] °C</th></tr><tr><th>Metal and liquids</th><th>Glass, porcelain, vitreous material</th><th>Molded material, plastic, rubber, wood</th></tr><tr><td rowspan="4">External surfaces of ME EQUIPMENT that are likely to be touched for a time “t”</td><td>t < 1 s</td><td>74</td><td>80</td><td>86</td></tr><tr><td>1 s ≤ t < 10 s</td><td>56</td><td>66</td><td>71</td></tr><tr><td>10 s ≤ t < 1 min</td><td>51</td><td>56</td><td>60</td></tr><tr><td>1 min ≤ t</td><td>48</td><td>48</td><td>48</td></tr></table>[a] These temperature limit values are applicable for touching the healthy skin of adults. They are not applicable when large areas of the skin (10 % of total body surface or more) can be in contact with a hot surface. This also applies in the case of skin contact with over 10 % of the head surface. Where this is the case, appropriate limits shall be determined and documented in the RISK MANAGEMENT FILE.</td><td>☒ N/A
☐ Parts: _____
Material:
☐ Metal and liquids
☐ Glass, porcelain, vitreous material
☐ Molded material, plastic, rubber, wood

Touch time:
☒ t < 1 s
☐ 1 s ≤ t < 10 s
☐ 10 s ≤ t < 1 min
☐ 1 min ≤ t</td></tr>
</table>

Issue Date: 2011-05-11
Revision Date: 2011-05-23

Miscellaneous - (002) 002. Client declaration table -Class II

	Table 24: APPLIED PART having contact with the PATIENT for a time "t" **Table 24—Allowable maximum temperatures for skin contact with ME EQUIPMENT APPLIED PARTS** Maximum temperature [a] [b] °C APPLIED PARTS of ME EQUIPMENT / Metal and liquids / Glass, porcelain, vitreous material / Molded material, plastic, rubber, wood APPLIED PART having contact with the PATIENT for a time "t" t < 1 min: 51 / 56 / 60 1 min ≤ t < 10 min: 48 / 48 / 48 10 min ≤ t: 43 / 43 / 43	☒ N/A ☐ Parts: _____ Material: ☐ Metal and liquids ☐ Glass, porcelain, vitreous material ☐ Molded material, plastic, rubber, wood Touch time: ☐ t < 1 s ☐ 1 s ≤ t < 10 s ☐ 10 s ≤ t < 1 min ☐ 1 min ≤ t
13 HAZARDOUS SITUATIONS and fault conditions	Electrical SINGLE FAULT CONDITIONS according to 8.1	

Supplement information:

SIGNATURE (Authorized person): ____ ZhangHui _____

Issue Date: 2011-05-11
Revision Date: 2011-05-23

Photographs - (001) 001. hybrid desktop housing type overall view

Photographs - (001) 001. hybrid desktop housing type overall view



Photographs - (002) 002. hybrid desktop housing type label side view

Photographs - (002) 002. hybrid desktop housing type label side view



Photographs - (003) 003. hybrid desktop housing type label side view

Photographs - (003) 003. hybrid desktop housing type label side view



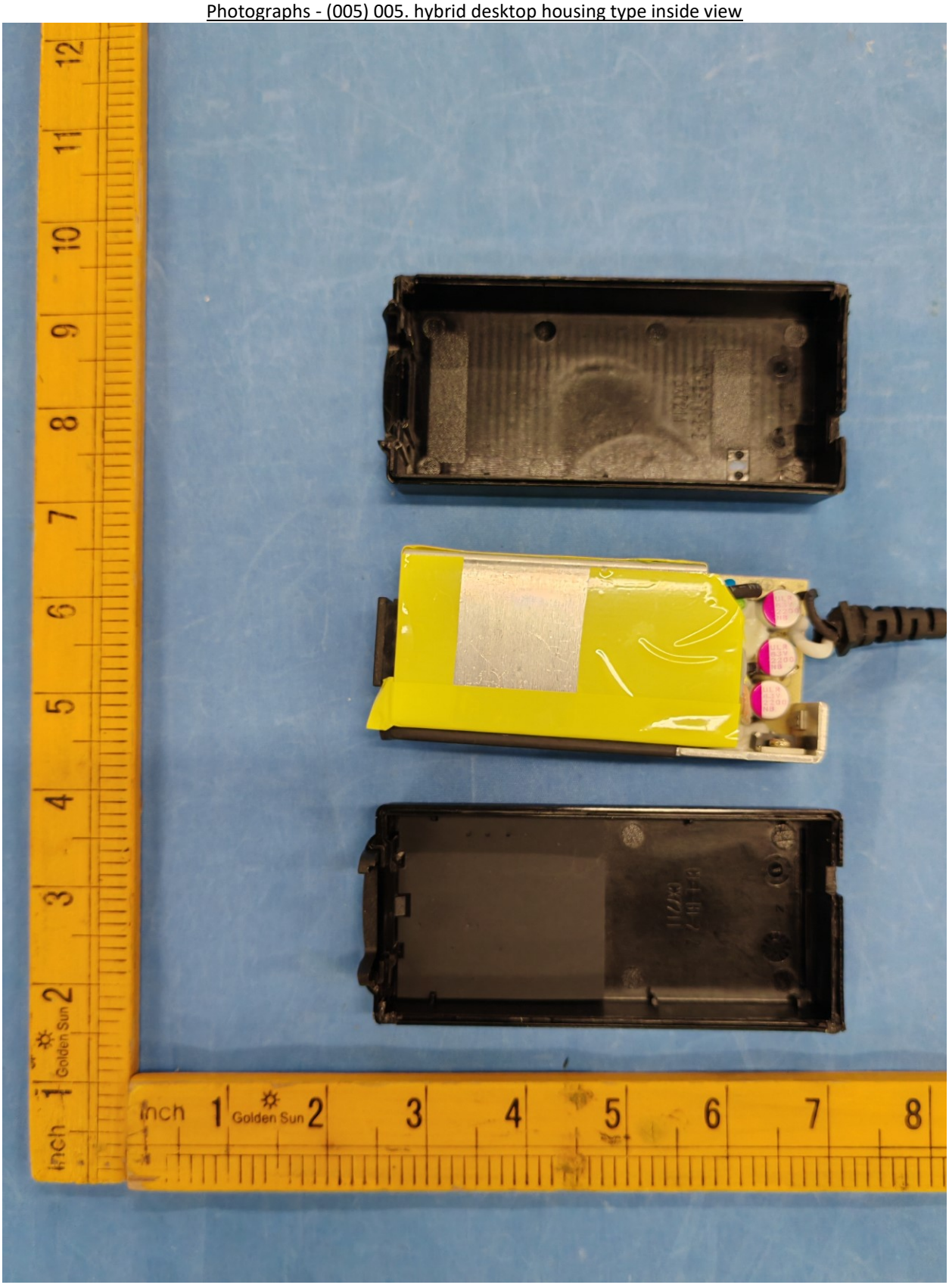
Photographs - (004) 004. hybrid desktop housing type side view

Photographs - (004) 004. hybrid desktop housing type side view



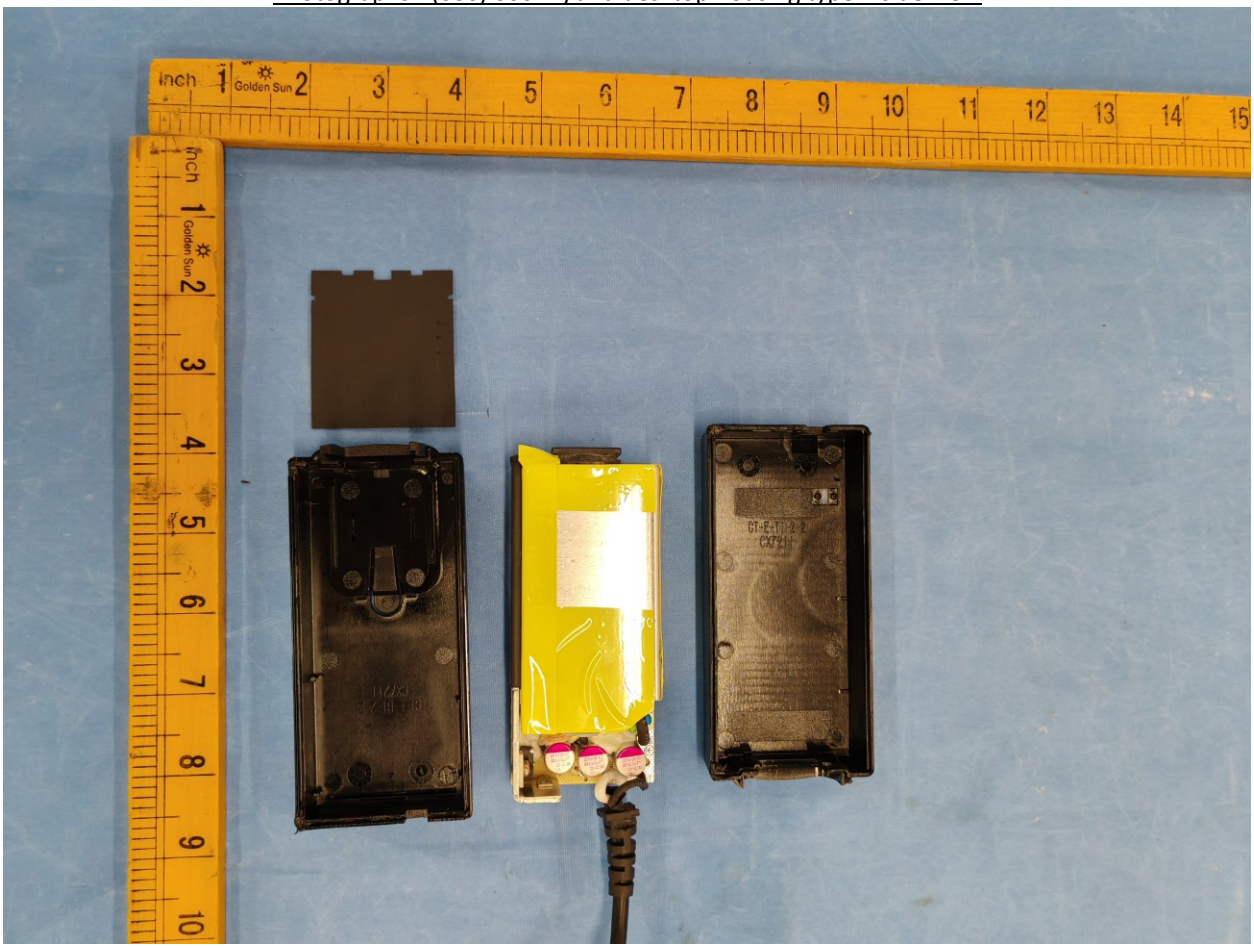
Photographs - (005) 005. hybrid desktop housing type inside view

Photographs - (005) 005. hybrid desktop housing type inside view



Photographs - (006) 006. hybrid desktop housing type inside view

Photographs - (006) 006. hybrid desktop housing type inside view



Photographs - (007) 006a. hybrid desktop housing type inside view

Photographs - (007) 006a. hybrid desktop housing type inside view



Photographs - (008) 007. desktop type overall view

Photographs - (008) 007. desktop type overall view



Photographs - (009) 007a. desktop type overall view

Photographs - (009) 007a. desktop type overall view



Photographs - (010) 008. desktop type label side view

Photographs - (010) 008. desktop type label side view



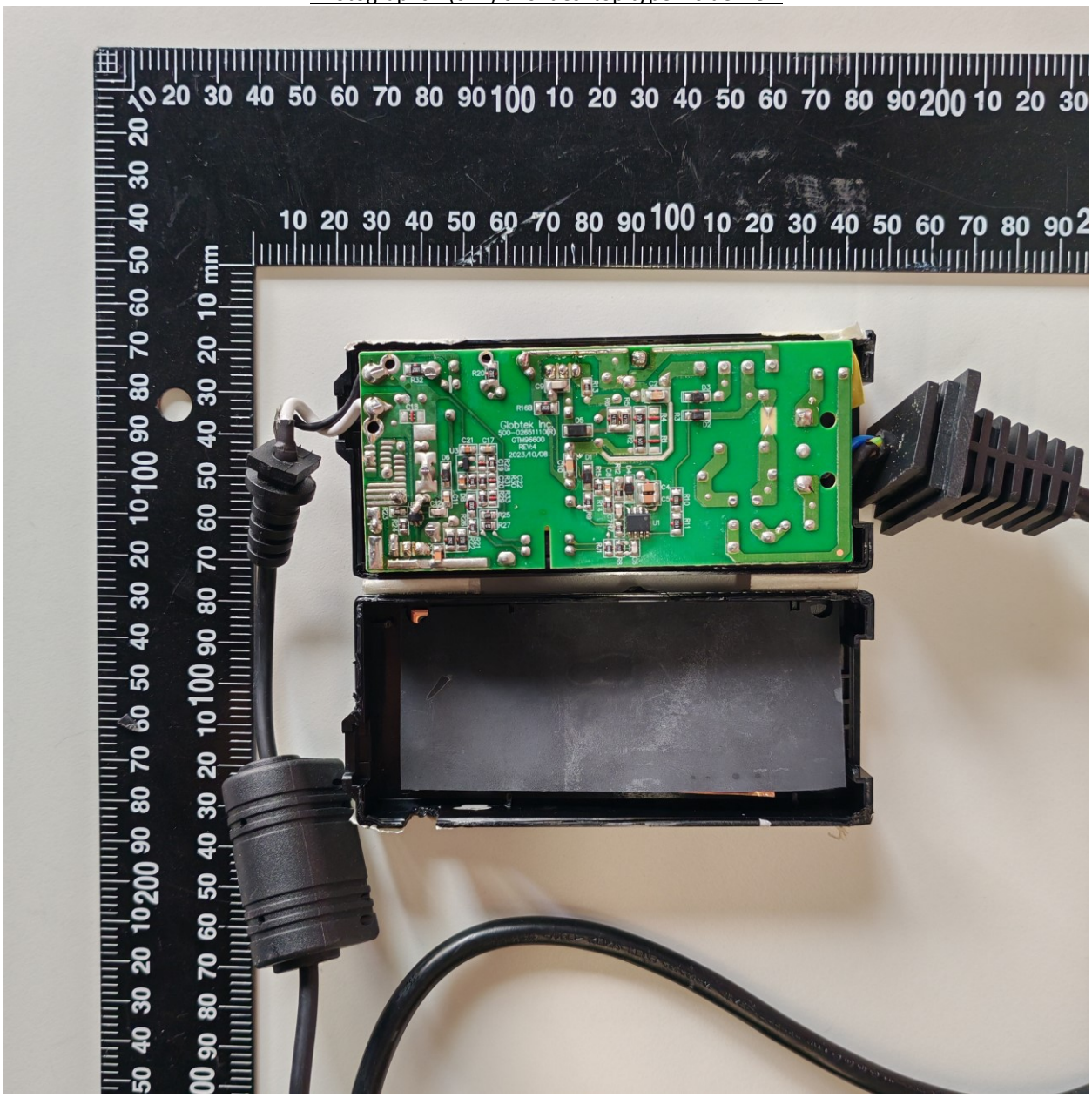
Photographs - (011) 009. desktop type side view.jpg

Photographs - (011) 009. desktop type side view.jpg



Photographs - (012) 010. desktop type inside view

Photographs - (012) 010. desktop type inside view



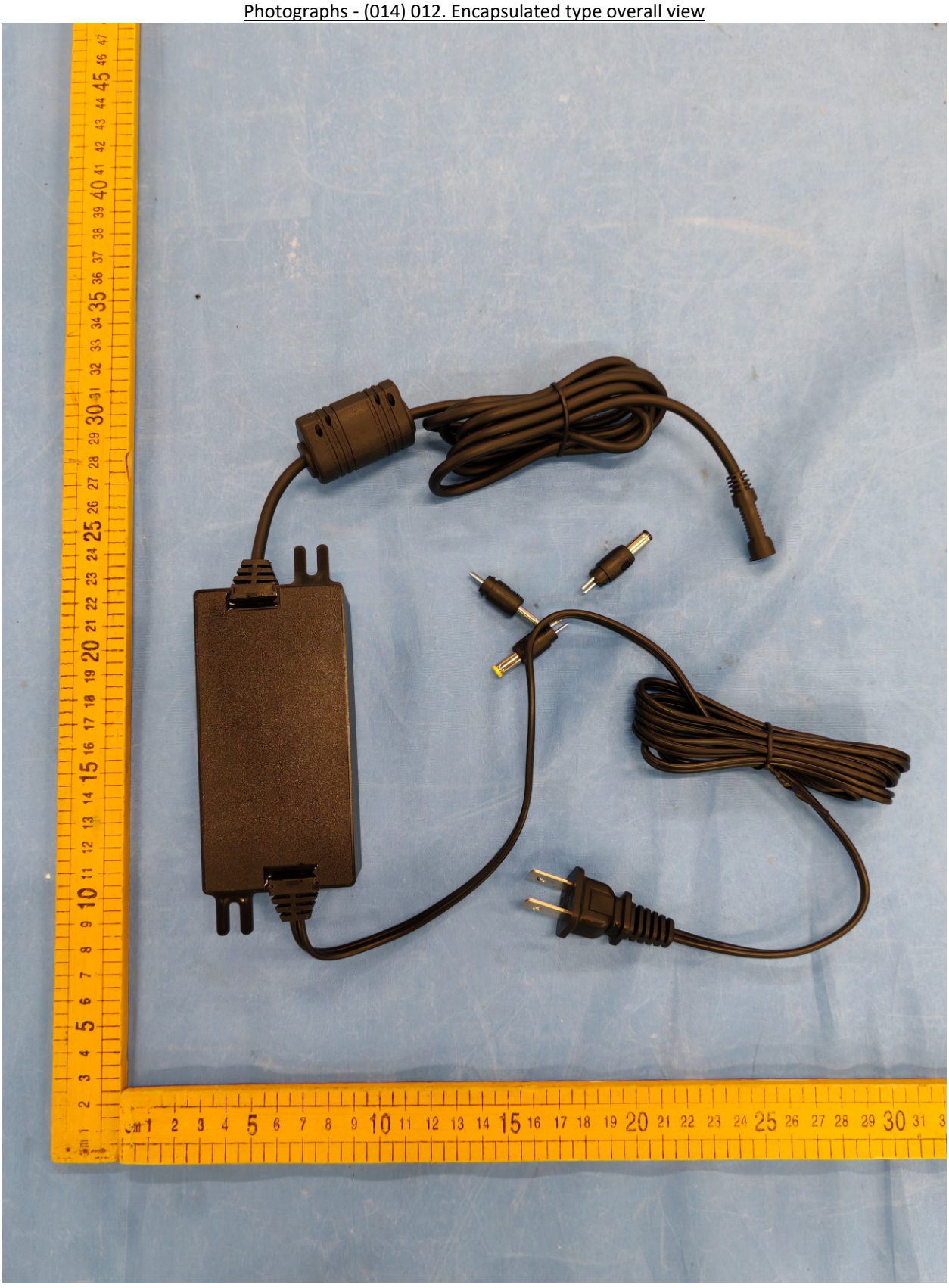
Photographs - (013) 011. desktop type inside view

Photographs - (013) 011. desktop type inside view



Photographs - (014) 012. Encapsulated type overall view

Photographs - (014) 012. Encapsulated type overall view



Photographs - (015) 013. Encapsulated type label side view.jpg

Photographs - (015) 013. Encapsulated type label side view.jpg



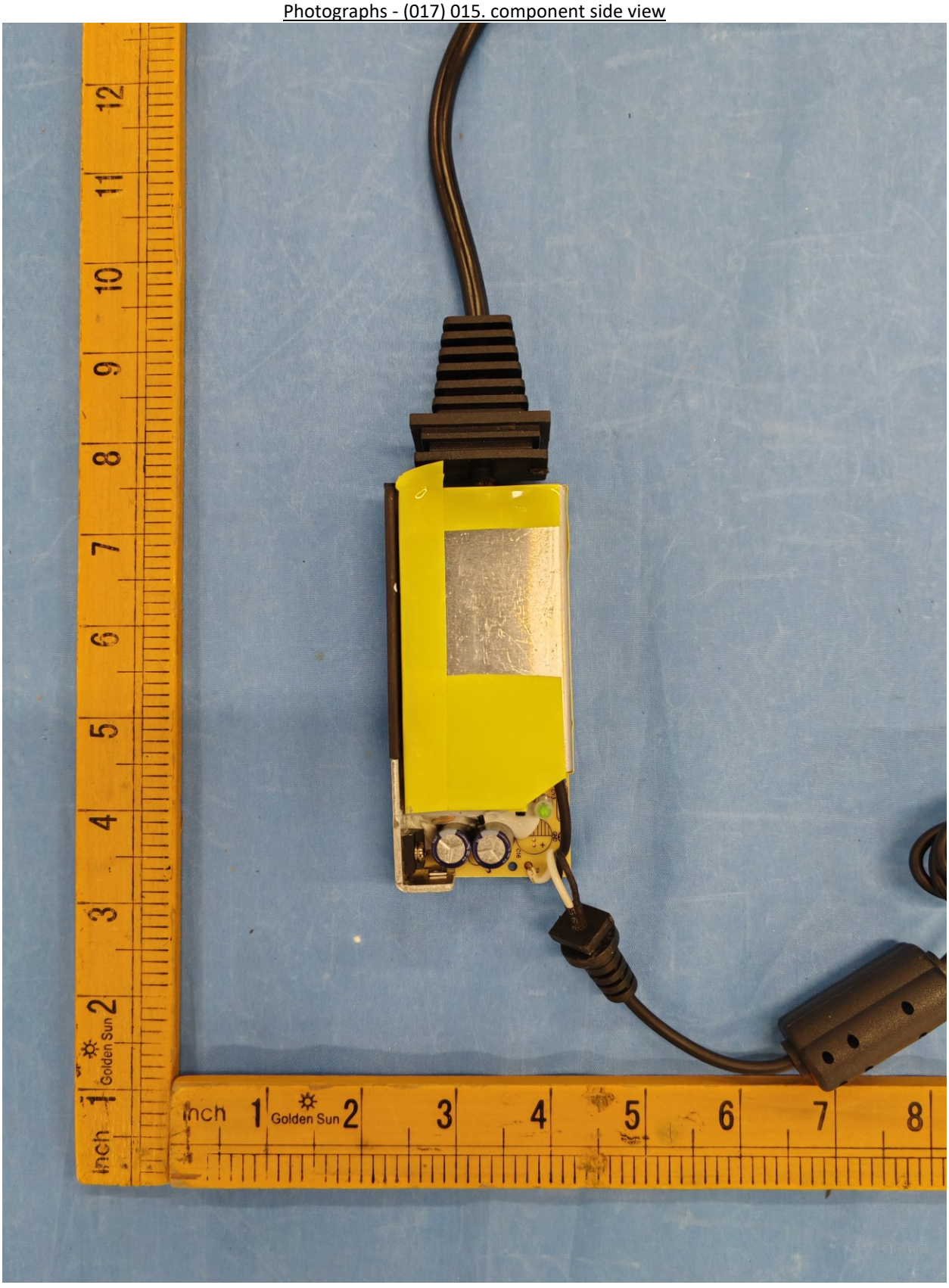
Photographs - (016) 014. Encapsulated type inside view.jpg

Photographs - (016) 014. Encapsulated type inside view.jpg



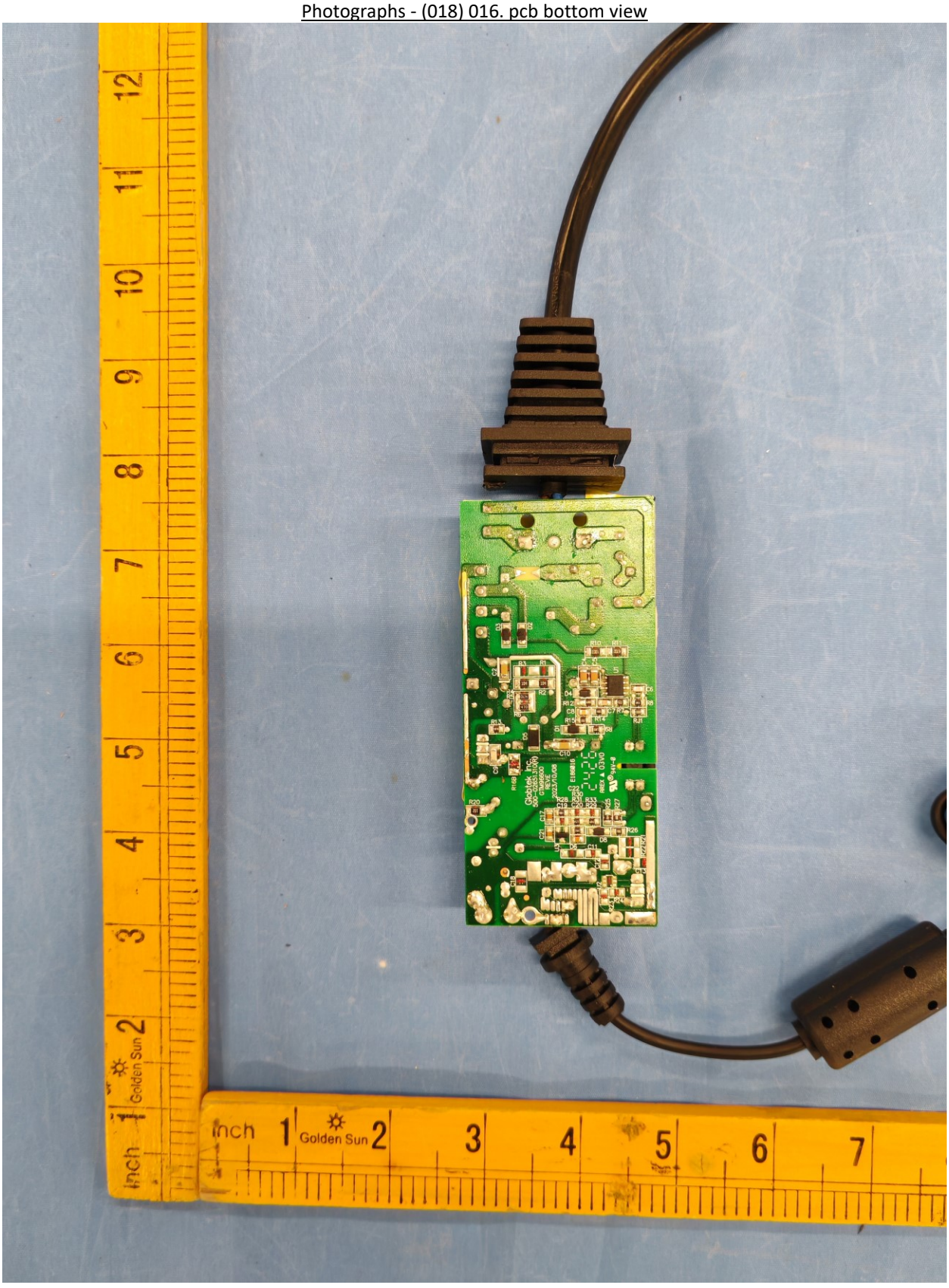
Photographs - (017) 015. component side view

Photographs - (017) 015. component side view



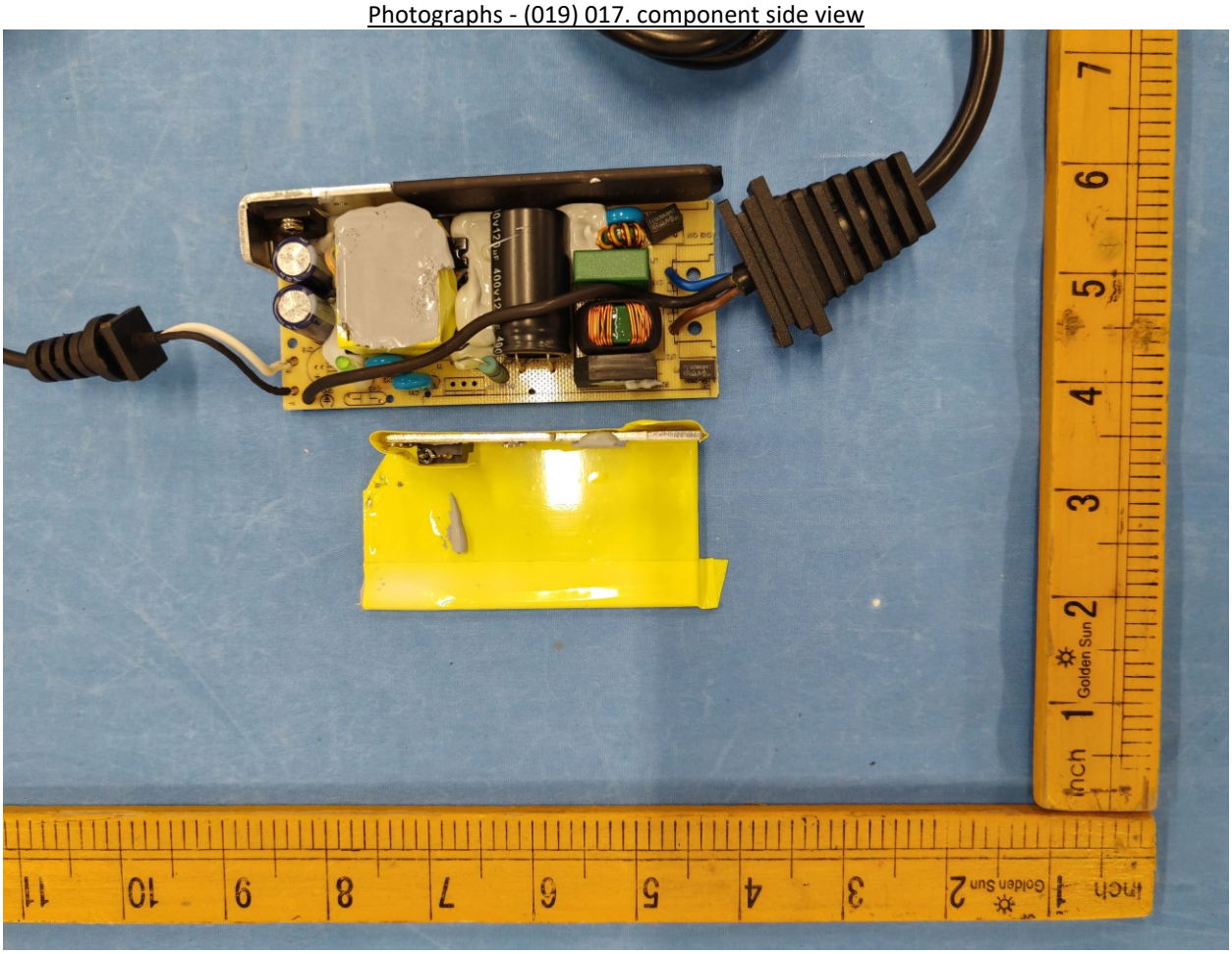
Photographs - (018) 016. pcb bottom view

Photographs - (018) 016. pcb bottom view



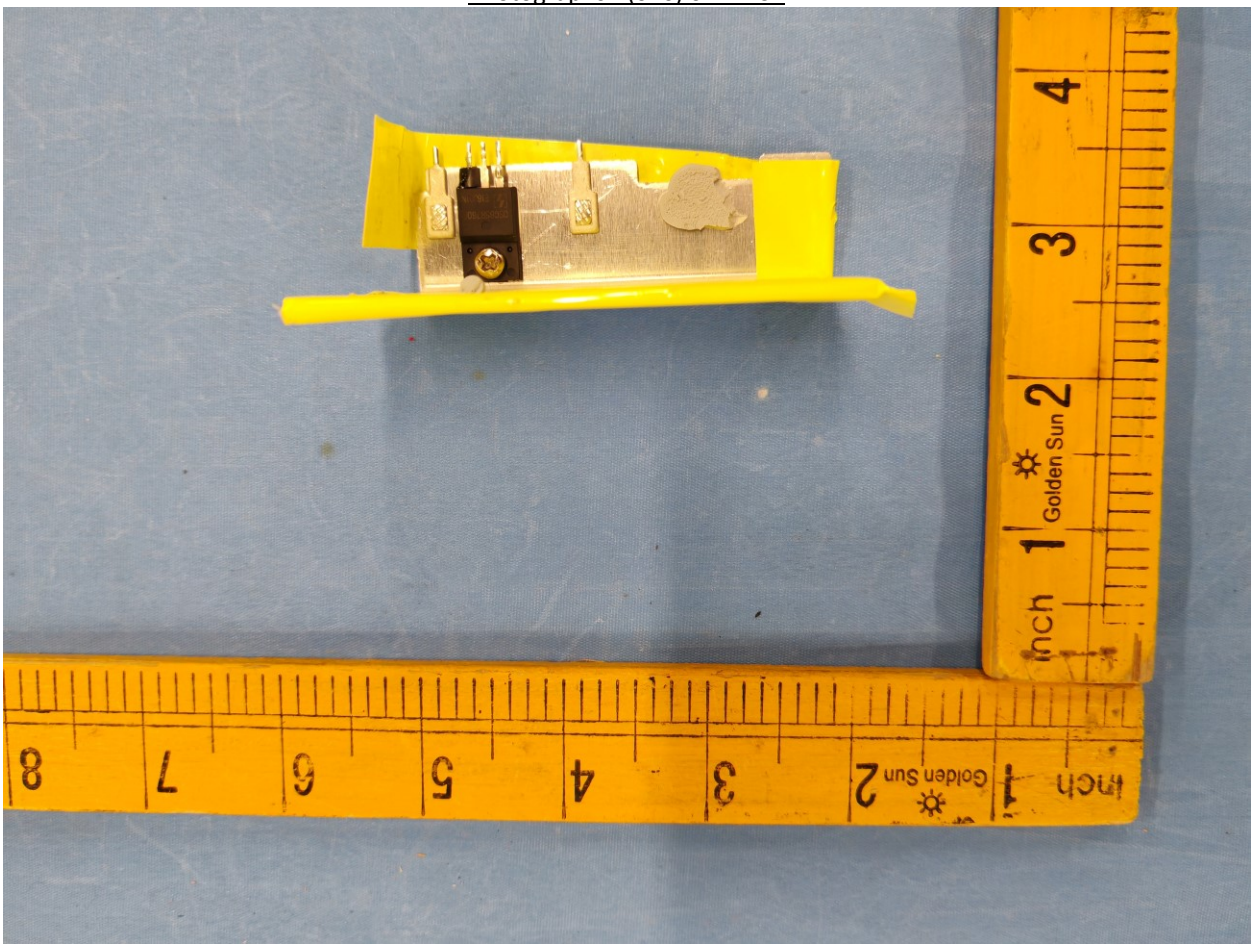
Photographs - (019) 017. component side view

Photographs - (019) 017. component side view



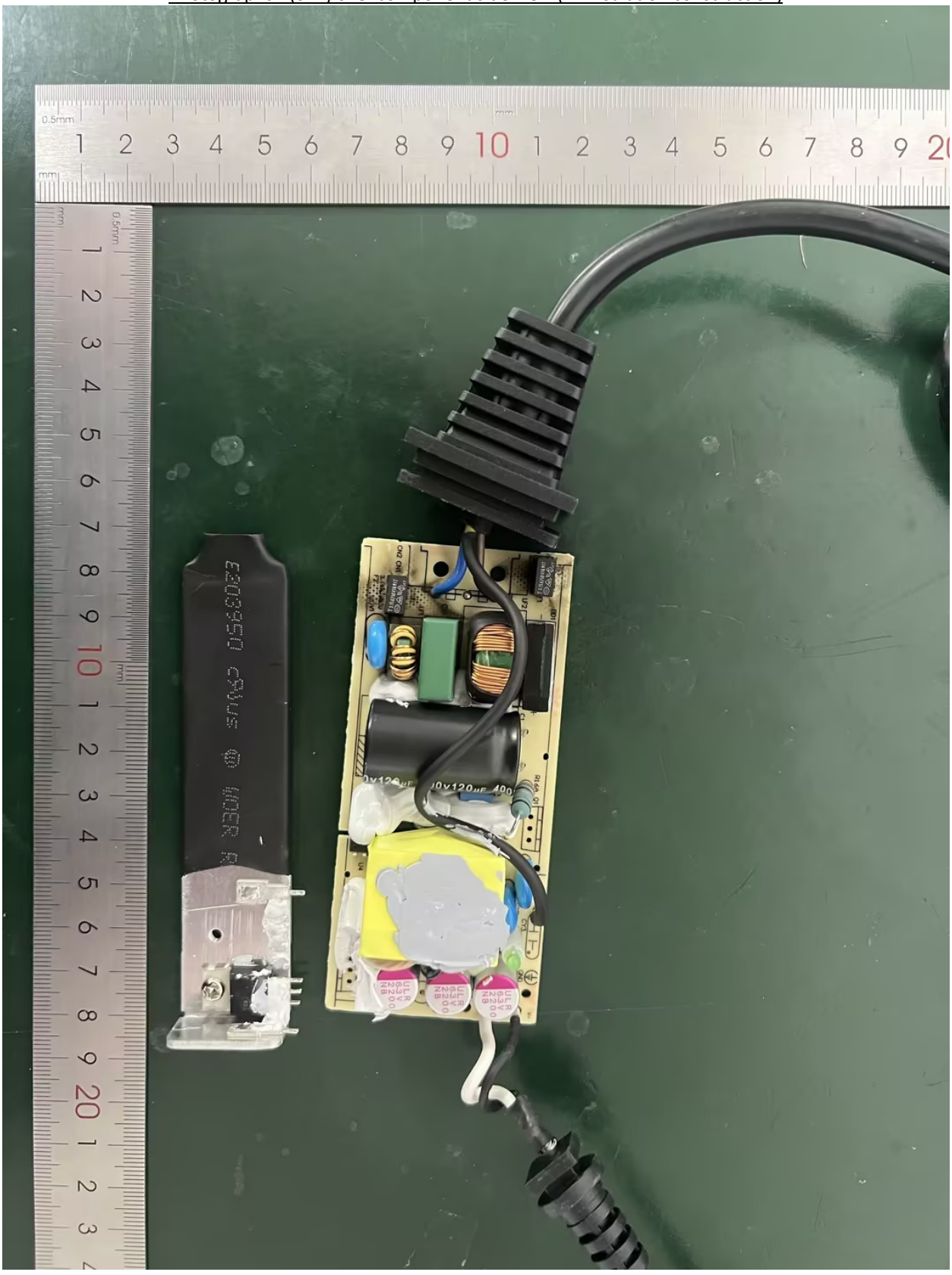
Photographs - (020) 017. HS1

Photographs - (020) 017. HS1



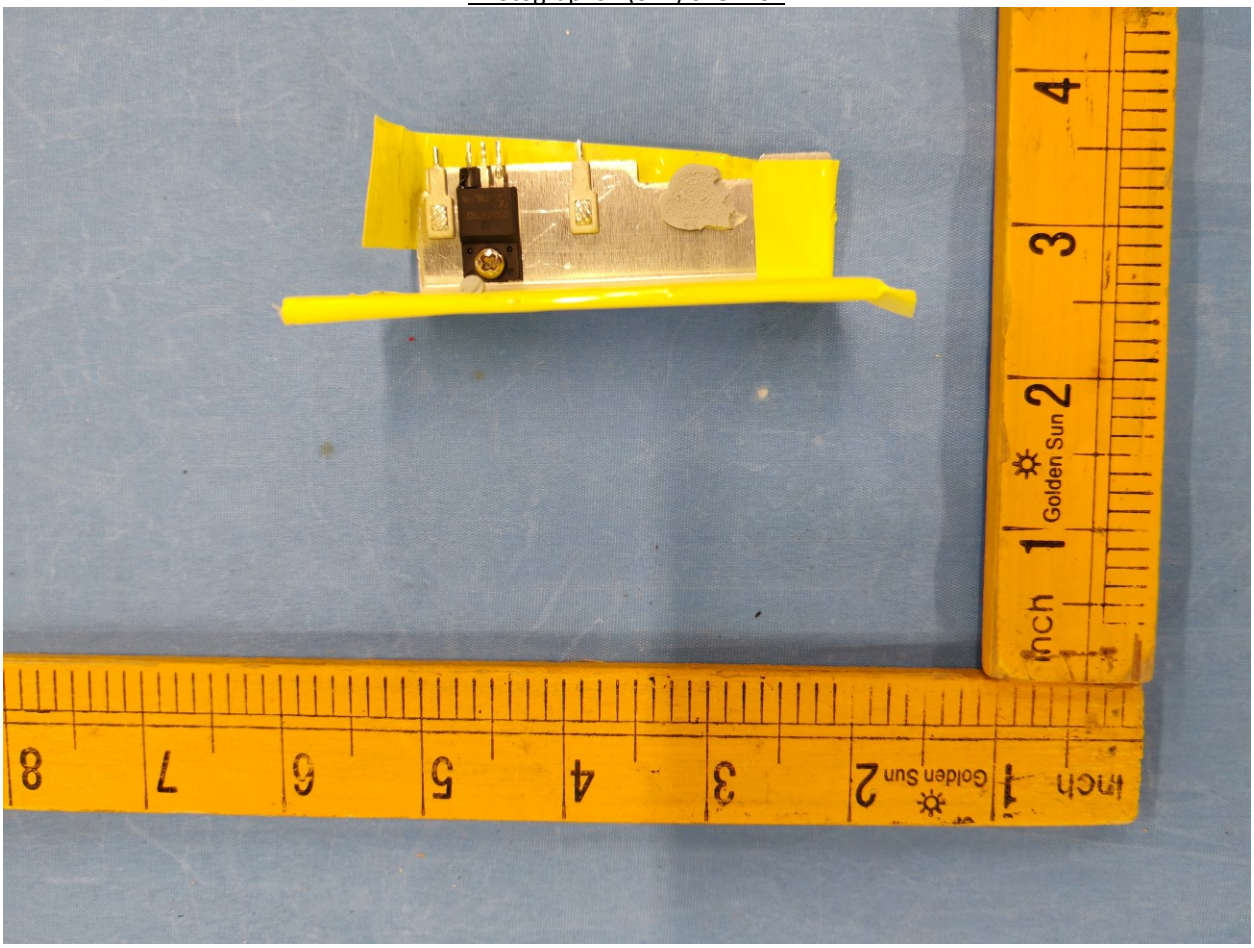
Photographs - (021) 018. component side view (F2 insulation construction)

Photographs - (021) 018. component side view (F2 insulation construction)



Photographs - (022) 018. HS1

Photographs - (022) 018. HS1



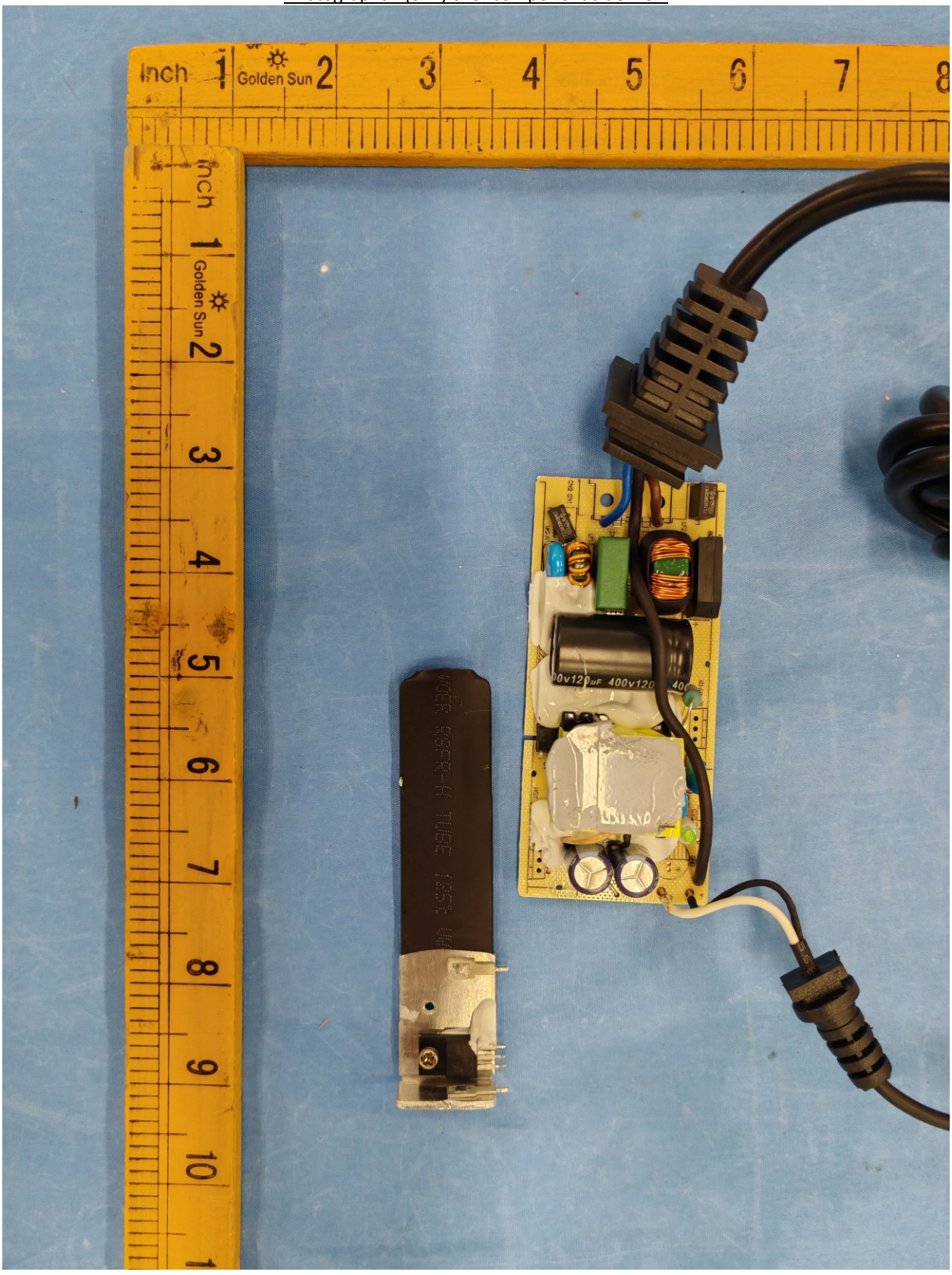
Photographs - (023) 019. component side view (F3 insulation construction)

Photographs - (023) 019. component side view (F3 insulation construction)



Photographs - (024) 019. component side view

Photographs - (024) 019. component side view



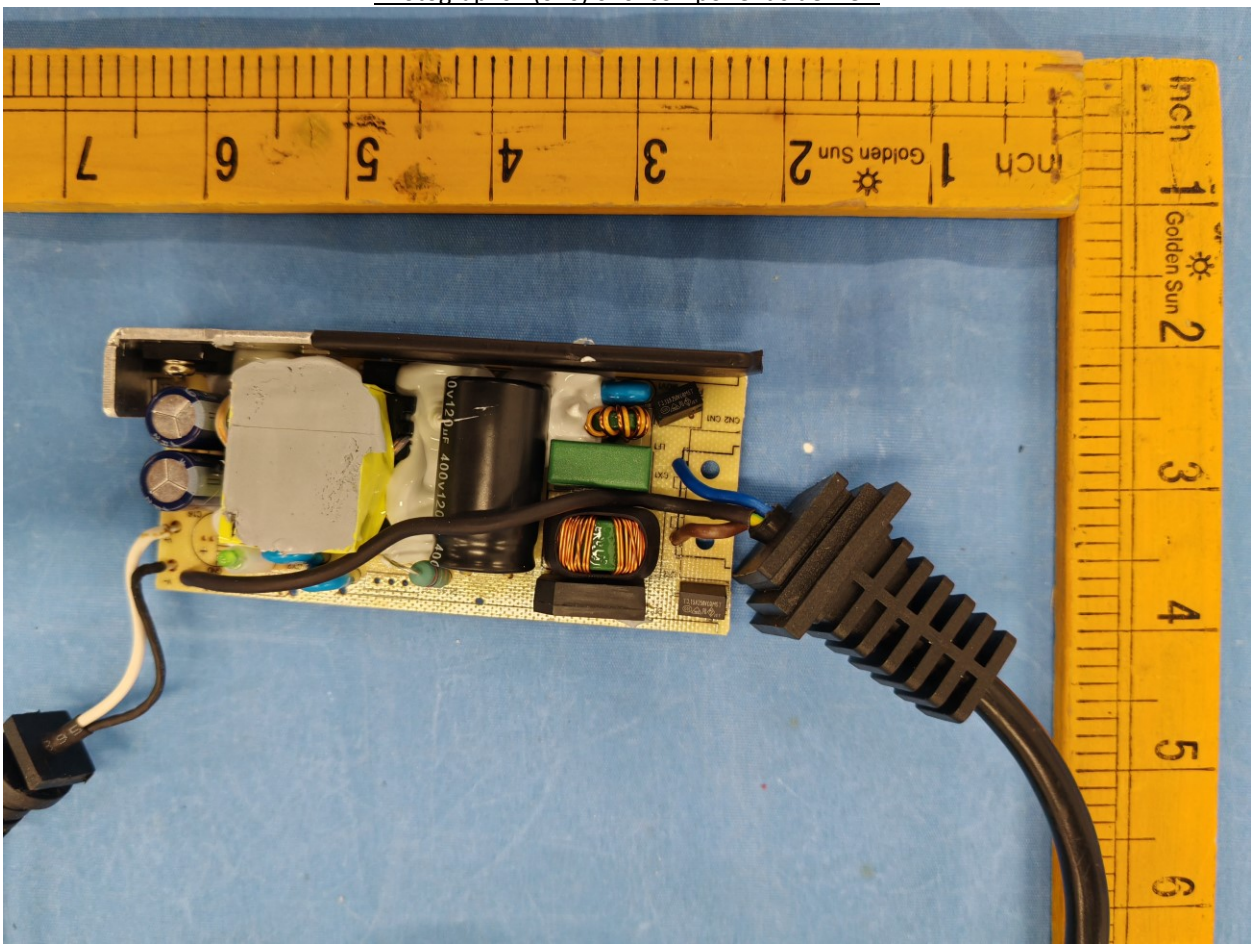
Photographs - (025) 020. component side view (E2 insulation construction)

Photographs - (025) 020. component side view (E2 insulation construction)



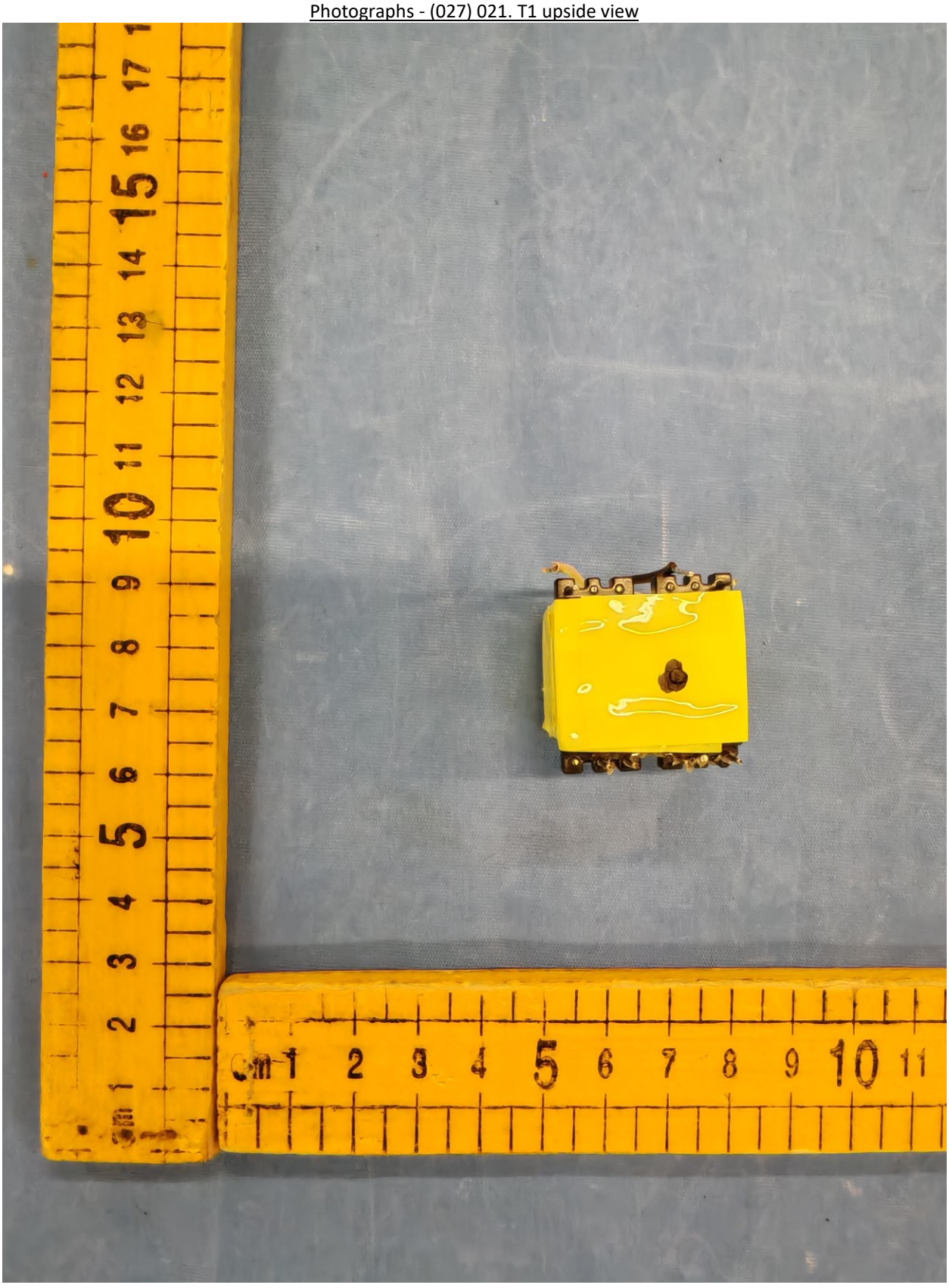
Photographs - (026) 020. component side view

Photographs - (026) 020. component side view



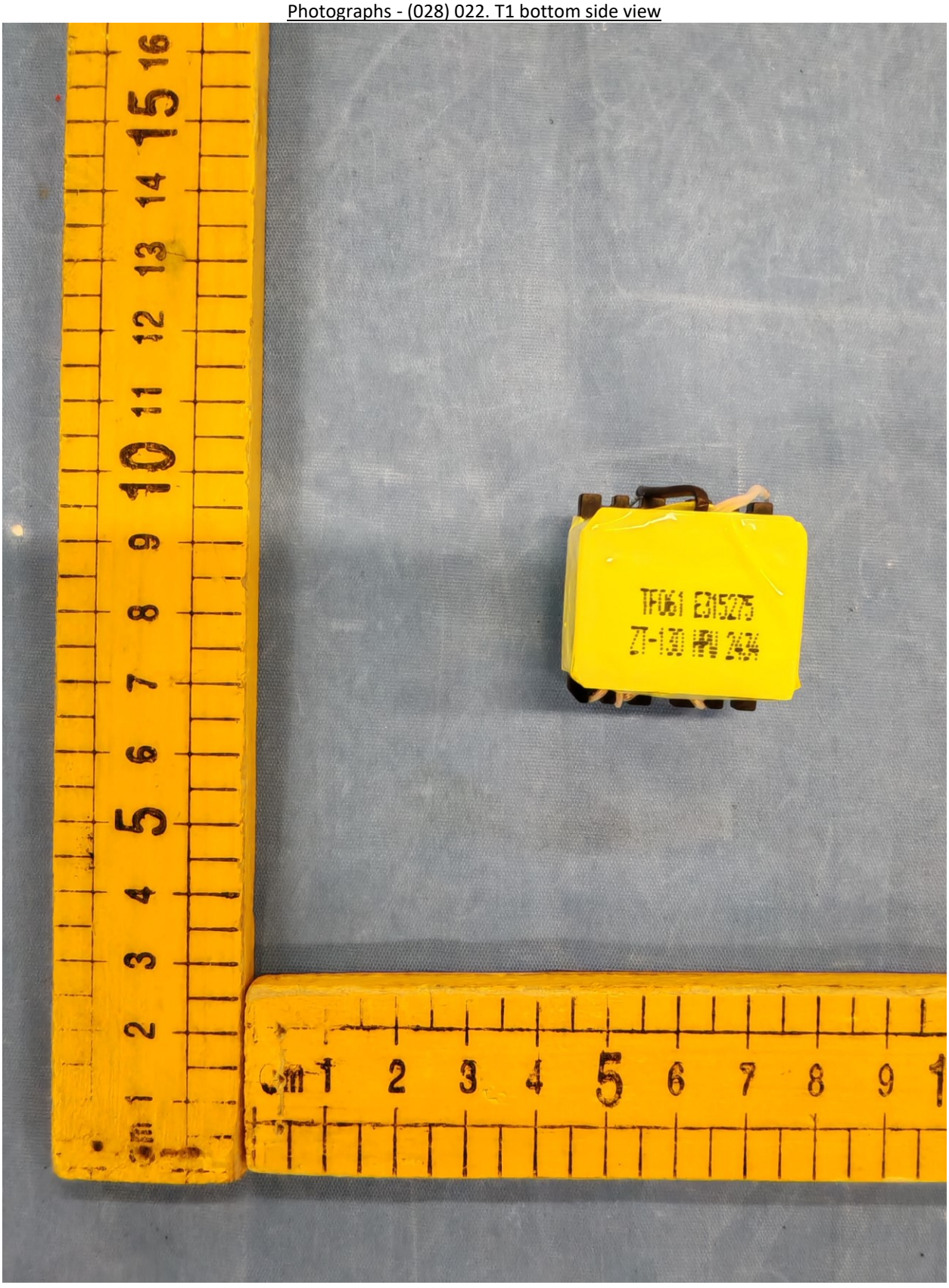
Photographs - (027) 021. T1 upside view

Photographs - (027) 021. T1 upside view



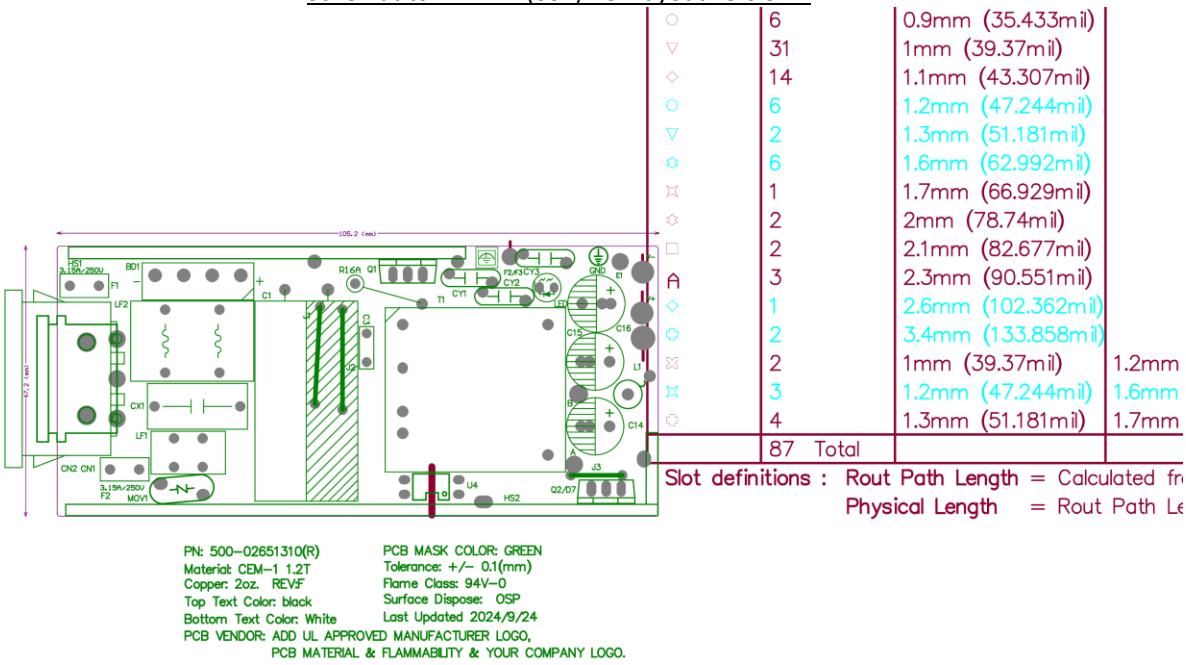
Photographs - (028) 022. T1 bottom side view

Photographs - (028) 022. T1 bottom side view



Schematics + PWB - (001) PCB layout version 1

Schematics + PWB - (001) PCB layout version 1



○	6	0.9mm (35.433mil)	
▽	31	1mm (39.37mil)	
◇	14	1.1mm (43.307mil)	
○	6	1.2mm (47.244mil)	
▽	2	1.3mm (51.181mil)	
☼	6	1.6mm (62.992mil)	
⌑	1	1.7mm (66.929mil)	
☼	2	2mm (78.74mil)	
□	2	2.1mm (82.677mil)	
A	3	2.3mm (90.551mil)	
◇	1	2.6mm (102.362mil)	
⌑	2	3.4mm (133.858mil)	
⌧	2	1mm (39.37mil)	1.2mm
⌑	3	1.2mm (47.244mil)	1.6mm
⌑	4	1.3mm (51.181mil)	1.7mm
	87 Total		

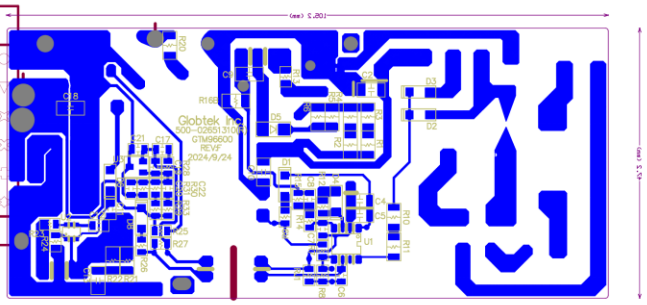
Slot definitions : Rout Path Length = Calculated fr
Physical Length = Rout Path Le

Schematics + PWB - (001) PCB layout version 1

Symbol	Hit Count	Tool Size	Physic
	2	1mm (39.37mil)	
	2	1.6mm (62.992mil)	
	1	2mm (78.74mil)	
	1	2.3mm (90.551mil)	
	1	2.6mm (102.362mil)	
	3	1.2mm (47.244mil)	1.6mm
	10	Total	

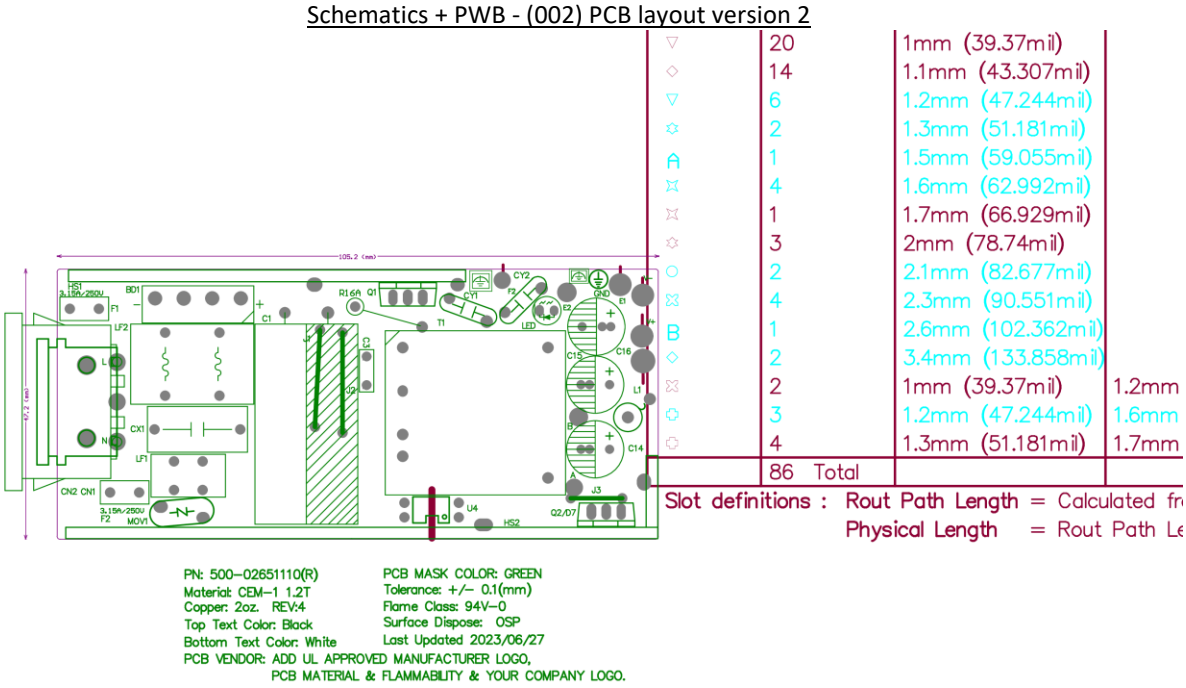
Slot definitions : Rout Path Length = Calculated fr

Physical Length = Rout Path L



Schematics + PWB - (002) PCB layout version 2

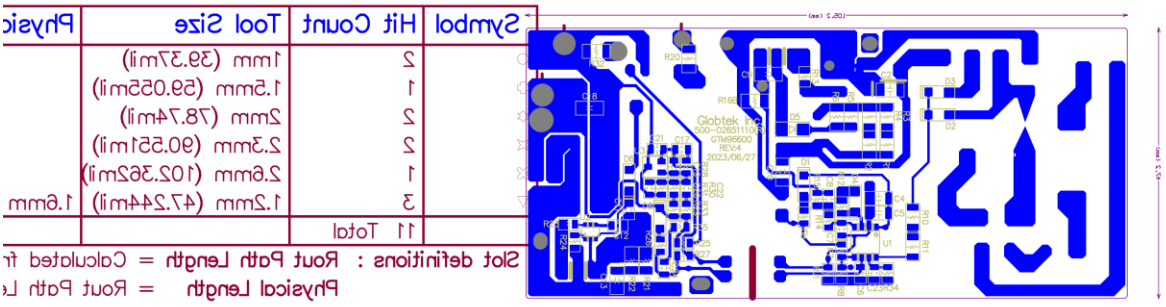
Schematics + PWB - (002) PCB layout version 2



PN: 500-02651110(R)
Material: CEM-1 1.2T
Copper: 2oz. REV:4
Top Text Color: Black
Bottom Text Color: White
PCB VENDOR: ADD UL APPROVED MANUFACTURER LOGO,
PCB MATERIAL & FLAMMABILITY & YOUR COMPANY LOGO.

PCB MASK COLOR: GREEN
Tolerance: +/- 0.1(mm)
Flame Class: 94V-0
Surface Dispose: OSP
Last Updated 2023/06/27

Schematics + PWB - (002) PCB layout version 2



----------END OF APPENDIX A----------

TEST RESULTS:

APPENDIX B: Test Datasheets Enclosures

The following tests have been performed as part of this report:

Standard	Clause No.	Test Name	Testing Location / Comments
IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020	4.11	Power Input	UL-CCIC Company Limited Guangzhou Branch / Room 101 & 401, Block A, R&D Building, Room 101, 201, 301, & 401, Block B, Electronic Building, No.8, Nanyun Er Road, Huangpu District Guangzhou China
IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020	5.7	Humidity Conditioning	UL-CCIC Company Limited Guangzhou Branch / Room 101 & 401, Block A, R&D Building, Room 101, 201, 301, & 401, Block B, Electronic Building, No.8, Nanyun Er Road, Huangpu District Guangzhou China
IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020	5.9.2	Determination of Accessible Parts	UL-CCIC Company Limited Guangzhou Branch / Room 101 & 401, Block A, R&D Building, Room 101, 201, 301, & 401, Block B, Electronic Building, No.8, Nanyun Er Road, Huangpu District Guangzhou China
IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020	7.1.3	Durability of Markings	UL-CCIC Company Limited Guangzhou Branch / Room 101 & 401, Block A, R&D Building, Room 101, 201, 301, & 401, Block B, Electronic Building, No.8, Nanyun Er Road, Huangpu District Guangzhou China

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020	8.4.2	Limitation of Voltage, Current or Power	UL-CCIC Company Limited Guangzhou Branch / Room 101 & 401, Block A, R&D Building, Room 101, 201, 301, & 401, Block B, Electronic Building, No.8, Nanyun Er Road, Huangpu District Guangzhou China
IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020	8.4.3	Voltage or Charge Limitation	UL-CCIC Company Limited Guangzhou Branch / Room 101 & 401, Block A, R&D Building, Room 101, 201, 301, & 401, Block B, Electronic Building, No.8, Nanyun Er Road, Huangpu District Guangzhou China
IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020	8.7	Leakage Current Tests	UL-CCIC Company Limited Guangzhou Branch / Room 101 & 401, Block A, R&D Building, Room 101, 201, 301, & 401, Block B, Electronic Building, No.8, Nanyun Er Road, Huangpu District Guangzhou China
IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020	8.7.4.5	Earth Leakage Current	UL-CCIC Company Limited Guangzhou Branch / Room 101 & 401, Block A, R&D Building, Room 101, 201, 301, & 401, Block B, Electronic Building, No.8, Nanyun Er Road, Huangpu District Guangzhou China
IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020	8.7.4.6	Touch Leakage Current	UL-CCIC Company Limited Guangzhou Branch / Room 101 & 401, Block A, R&D Building, Room 101, 201, 301, & 401, Block B, Electronic Building, No.8, Nanyun Er Road,

			Huangpu District Guangzhou China
IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020	8.7.3 e)	Non-Frequency-Weighted Leakage Current	UL-CCIC Company Limited Guangzhou Branch / Room 101 & 401, Block A, R&D Building, Room 101, 201, 301, & 401, Block B, Electronic Building, No.8, Nanyun Er Road, Huangpu District Guangzhou China
IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020	8.8.3	Dielectric Voltage Withstand	UL-CCIC Company Limited Guangzhou Branch / Room 101 & 401, Block A, R&D Building, Room 101, 201, 301, & 401, Block B, Electronic Building, No.8, Nanyun Er Road, Huangpu District Guangzhou China
IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020	8.8.4.1	Ball Pressure	UL-CCIC Company Limited Guangzhou Branch / Room 101 & 401, Block A, R&D Building, Room 101, 201, 301, & 401, Block B, Electronic Building, No.8, Nanyun Er Road, Huangpu District Guangzhou China
IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020	8.11.3.5	Cord Anchorage	UL-CCIC Company Limited Guangzhou Branch / Room 101 & 401, Block A, R&D Building, Room 101, 201, 301, & 401, Block B, Electronic Building, No.8, Nanyun Er Road, Huangpu District Guangzhou China
IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020	8.11.3.6	Cord Bending	UL-CCIC Company Limited Guangzhou Branch / Room 101 & 401, Block A, R&D Building, Room 101, 201, 301, & 401, Block B, Electronic

			Building, No.8, Nanyun Er Road, Huangpu District Guangzhou China
IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020	11	Temperature	UL-CCIC Company Limited Guangzhou Branch / Room 101 & 401, Block A, R&D Building, Room 101, 201, 301, & 401, Block B, Electronic Building, No.8, Nanyun Er Road, Huangpu District Guangzhou China
IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020	11.6.5	Harmful Ingress (Water and Particulates)	UL-CCIC Company Limited Guangzhou Branch / Room 101 & 401, Block A, R&D Building, Room 101, 201, 301, & 401, Block B, Electronic Building, No.8, Nanyun Er Road, Huangpu District Guangzhou China
IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020	13	Abnormal Operation Testing	UL-CCIC Company Limited Guangzhou Branch / Room 101 & 401, Block A, R&D Building, Room 101, 201, 301, & 401, Block B, Electronic Building, No.8, Nanyun Er Road, Huangpu District Guangzhou China
IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020	15.3.2	Enclosure Force	UL-CCIC Company Limited Guangzhou Branch / Room 101 & 401, Block A, R&D Building, Room 101, 201, 301, & 401, Block B, Electronic Building, No.8, Nanyun Er Road, Huangpu District Guangzhou China
IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020	15.3.3	Enclosure Impact	UL-CCIC Company Limited Guangzhou Branch / Room 101 & 401, Block A, R&D Building, Room 101, 201,

			301, & 401, Block B, Electronic Building, No.8, Nanyun Er Road, Huangpu District Guangzhou China
IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020	15.3.4	Drop Impact	UL-CCIC Company Limited Guangzhou Branch / Room 101 & 401, Block A, R&D Building, Room 101, 201, 301, & 401, Block B, Electronic Building, No.8, Nanyun Er Road, Huangpu District Guangzhou China
IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020	15.3.6	Mold Stress Relief	UL-CCIC Company Limited Guangzhou Branch / Room 101 & 401, Block A, R&D Building, Room 101, 201, 301, & 401, Block B, Electronic Building, No.8, Nanyun Er Road, Huangpu District Guangzhou China
IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020	15.5.1.2	Transformer Short Circuit	UL-CCIC Company Limited Guangzhou Branch / Room 101 & 401, Block A, R&D Building, Room 101, 201, 301, & 401, Block B, Electronic Building, No.8, Nanyun Er Road, Huangpu District Guangzhou China
IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020	15.5.1.3	Transformer Overload	UL-CCIC Company Limited Guangzhou Branch / Room 101 & 401, Block A, R&D Building, Room 101, 201, 301, & 401, Block B, Electronic Building, No.8, Nanyun Er Road, Huangpu District Guangzhou China

NOTE: If testing location is blank then the test was performed at the CB Testing Laboratory as specified at the beginning of this report.

The following datasheet enclosures are provided in this section of the report. If blank, no separate enclosures are attached.

Enclosures

Supplement ID	Description
-	No separate datasheet enclosures attached.

---------- END OF APPENDIX B ----------

National Differences

The following National Differences are included in this Report. If not 'Selected', the device was not evaluated to these Differences.

If selected, Group Differences are applicable for CENELEC member countries: Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Selected? (y/n)	Group / Country	Standard	Abbreviation
Yes	United States of America	AAMI ES60601-1:2005,ES60601-1:2005/AMD1 1:2012 , ES60601-1:2005/AMD2:2021	US
Yes	Canada	CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14	CAN

ATTACHMENT to TRF IEC60601_1U			
Clause	Requirement + Test	Result - Remark	Verdict

ATTACHMENT TO TEST REPORT
IEC 60601-1:2005, IE60601-1:2005/AMD1:2012, IEC60601-1:2005/AMD2:2020
US NATIONAL DIFFERENCES
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

Differences according to ..... :	National standard AAMI ES60601-1:2005, AAMI ES60601-1:2005/AMD1:2012, AAMI ES60601-1:2005/AMD2:2021
TRF template used:.....:	IECEE OD-2020-F3:2022, Ed. 1.2
Attachment Form No. ..... :	US_ND_IEC60601_1U
Attachment Originator..... :	UL Solutions (US)
Master Attachment..... :	2024-05-17

Copyright © 2024 IEC System for Conformity Testing and Certification of Electrical Equipment (IECEE), Geneva, Switzerland. All rights reserved.

	National Differences		
4.8	Components of ME EQUIPMENT		Pass
	b) where there is no relevant IEC/ISO standard, the relevant ANSI standard applied; if no relevant ANSI standard exists, the requirements of this standard were applied. (Replacement of clause 4.8 b)		Pass
4.10.2	SUPPLY MAINS FOR ME EQUIPMENT AND ME SYSTEMS		Pass
	(Replacement to reflect agreement with the National Electrical Code (NEC): The reference to "500 V" replaced with "600 V" in the second and third dashes.		N/A
	(Addition to reflect agreement with the NEC) In the text of the second-to-last dash of this sub-clause, "and the NEC" added after reference to "IEC 60364-4-41"		N/A
6.0	Classification of ME EQUIPMENT and ME SYSTEMS		Pass
6.6	Mode of operation		Pass
	(Addition to reflect agreement with NFPA 70) X-Ray systems are classified as long time operation (> 5 min) or momentary operation (< 5 sec).		N/A
7.0	ME EQUIPMENT identification, marking and documents		Pass

ATTACHMENT to TRF IEC60601_1U			
Clause	Requirement + Test	Result - Remark	Verdict
7.2.11	Mode of operation		Pass
	(Addition to reflect agreement with NFPA 70) X-Ray systems are marked as long time operation or momentary operation.		N/A
7.2.22	(Addition of new item) Colours of medical gas cylinders		N/A
	To reflect agreement with NFPA 99: Cylinders containing medical gases and their connection points are coloured in accordance with the requirements of NFPA 99.		N/A
8	Protection against electrical hazards from ME EQUIPMENT		Pass
8.2	Requirements related to power sources		N/A
	(Addition to reflect agreement with the NEC) All FIXED ME EQUIPMENT and PERMANENTLY INSTALLED ME EQUIPMENT are CLASS I ME EQUIPMENT.		N/A
8.6.1	Application of requirements		N/A
	(Addition to reflect agreement with NFPA 99) The enclosure of X-ray ME EQUIPMENT operating over 600 Vac, 850 Vdc MAINS VOLTAGE, or containing voltages up to 50 V peak and enclosed in protectively earthed enclosure as well as connections to X-ray tubes and other high voltage components that include high voltage shielded cables are PROTECTIVELY EARTHED.		N/A
	(Addition to reflect agreement with NFPA 99) Non-current carrying conductive parts of X-Ray ME EQUIPMENT likely to become energized are PROTECTIVELY EARTHED		N/A
8.7.3	Allowable values		Pass
	(Deletion to reflect agreement with NFPA 99 which does not allow for allowance greater than the stated values) Delete the second sentence and note to sub-clause 8.7.3 d) so that it reads: d) The allowable values of the EARTH LEAKAGE CURRENT are 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION		Pass
8.11	MAINS PARTS, components and layout		Pass

ATTACHMENT to TRF IEC60601_1U			
Clause	Requirement + Test	Result - Remark	Verdict
	(Addition to reflect agreement with the NEC) Permanently connected ME EQUIPMENT has provision for the connection of one of the wiring systems that is in accordance with the NEC.		N/A
	Exception: Fixed and stationary X-ray ME EQUIPMENT supplied from a branch circuit rated at 30 A or less, and ME EQUIPMENT that is not strictly portable but obviously is intended to be stationary, may be acceptable if provided with a length of attached hard service flexible cord - such as Type S, or the equivalent, for supply connection.		N/A
	The installation of connecting cords between EQUIPMENT parts meets the requirements of the NEC, as applicable. Cable used as external interconnection between units are as follows:	Component, to be evaluated in end-product	N/A
	1) If exposed to abuse, the cables are Type SJT, SJTO, SJO, ST, SO, STO, or equivalent flexible cord or similar multiple-conductor appliance-wiring material such as computer cable		N/A
	2) If not exposed to abuse, the cables are as indicated in item 1) above or are: i) Type SPT-2, SP-2, or SPE-2, or equivalent, ii) Type SVr, SVRO, SVE, or equivalent flexible cord or similar multiple-conductor appliance wiring material, or iii) An assembly of insulated wires each with a nominal insulation thickness of 0.8 mm (1/32 inch) or more, enclosed in acceptable insulating tubing having a nominal wall thickness of 0.8 mm (1/32 inch) or more.		N/A
	Receptacles provided as part of ME EQUIPMENT or ME SYSTEMS for use in the patient care areas of paediatric wards, rooms, or areas are listed tamper resistant or employ a listed tamper resistant cover in accordance with the NEC.		N/A
	b) For ME EQUIPMENT provided with NEMA configuration non-locking plug types 120 V/15 A, 125 V/20 A, 250 V/15 A, 250 V/20 A “Hospital Grade” mains plug is provided and the POWER SUPPLY CORD is marked.		N/A

ATTACHMENT to TRF IEC60601_1U			
Clause	Requirement + Test	Result - Remark	Verdict
8.11.3.2	(Addition to reflect agreement with the NEC) The flexible cord is of a type that is acceptable for the particular application. It is acceptable for use at a voltage not less than the rated voltage of the appliance and has an ampacity, as given in the NEC, not less than the current rating of the appliance:	See appended Table 8.10	Pass
8.11.3.3	Cross-sectional area of POWER SUPPLY CORDS	Min. 18AWG	Pass
	(Addition to reflect agreement with NFPA 99) For X-Ray ME EQUIPMENT with an attachment plug, the current rating on a hospital grade plug should be 2X the maximum input current of the equipment.	Component, to be evaluated in end product	N/A
	1) If exposed to abuse, the cables are Type SJT, SJTO, SJO, ST, SO, STO, or equivalent flexible cord or similar multiple-conductor appliance-wiring material such as computer cable.		N/A
	2) If not exposed to abuse, the cables are as indicated in item 1) above or are: i) Type SPT-2, SP-2, or SPE-2, or equivalent, ii) Type SVr, SVRO, SVE, or equivalent flexible cord or similar multiple-conductor appliance wiring material, or iii) An assembly of insulated wires each with a nominal insulation thickness of 0.8 mm (1/32 inch) or more, enclosed in acceptable insulating tubing having a nominal wall thickness of 0.8 mm (1/32 inch) or more.		N/A
	Receptacles provided as part of ME EQUIPMENT or ME SYSTEMS for use in the patient care areas of paediatric wards, rooms, or areas are listed tamper resistant or employ a listed tamper resistant cover in accordance with the NEC.	Component, to be evaluated in end product	N/A
	b) For ME EQUIPMENT provided with NEMA configuration non-locking plug types 120 V/15 A, 125 V/20 A, 250 V/15 A, 250 V/20 A “Hospital Grade” mains plug is provided and the POWER SUPPLY CORD is marked.	Component, to be evaluated in end product	N/A

IEC60601_1U ATTACHMENT			
Clause	Requirement + Test	Result - Remark	Verdict

ATTACHMENT TO TEST REPORT
IEC 60601-1
CANADA NATIONAL DIFFERENCES
Medical electrical equipment — Part 1: General requirements for basic safety and essential performance

Differences according to ..... :	Canadian National standard: CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14
TRF template used:.....:	IECEE OD-2020-F3, Ed. 1.1
Attachment Form No. ..... :	CA_ND_IEC60601_1U
Attachment Originator..... :	CSA Group
Master Attachment..... :	Dated 2022-08-12

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Note *: IEC CANADIAN NATIONAL DIFFERENCES in Canada are called CANADIAN DEVIATIONS.

	Canadian National Differences		
	Canadian National Differences		Pass
1	Scope, object and related standards		Pass
1.1	Scope		Pass
	[Replace the first paragraph with the following] This Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS designed to be used in accordance with CSA C22.1 (Canadian Electrical Code, Part I) and CSA Z32.		Pass
	[Add the following note] Note 1A: In the IEC 60601 Standards series adopted for use in Canada, the Canadian standards may modify, replace, or delete requirements contained in the IEC standard as appropriate to the ME EQUIPMENT and ME SYSTEMS under evaluation, and they may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements		-
1.3	Collateral standards		Pass
	[Replace this clause with the following] Applicable Canadian 60601 collateral standards become normative at the date of their publication		Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	and apply together with this Standard.		
1.4	Particular standards		N/A
	[Replace this clause with the following] Applicable Canadian 60601/80601 particular standards may modify, replace, or delete requirements contained in this Standard. The requirement of a Canadian 60601/80601 particular safety standard takes priority over this Standard.		N/A
2	Normative references		Pass
	In this CSA Group adoption, any reference to International Standards shall be replaced by the relevant National Standard of Canada. Note 1DV: For additional information about normative Standards in Canada, refer to the Canadian Electrical Code, Part I, Appendix A. Where reference is made to CSA Group Standards, such reference are considered to refer to the latest edition and all amendments published to that edition. This Standard refers to the following Standards, and the years shown indicate the latest editions available at the time of printing: CSA Group B51-09 Boiler, pressure vessel, and pressure piping code C22.1-21 Canadian Electrical Code, Part I C22.2 No. 0:20 General requirements — Canadian Electrical Code, Part II C22.2 No. 0.4-17 Bonding of electrical equipment C22.2 No. 21-95 (R2009) Cord sets and power supply cords C22.2 No. 42-10 General use receptacles, attachment plugs, and similar wiring devices C22.2 No. 49-10 Flexible cords and cables C22.2 No. 100:14 (R2019) Motors and generators C22.2 No. 248 series of Standards Low-voltage fuses		Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	C22.2 No. 308-18 Cord reels and multi-outlet assemblies CAN/CSA-E61558-2-1-03 (R2012) Safety of power transformers, power supply units and similar — Part 2: Particular requirements for separating transformers for general use CSA C22.2 No. 62368-1:19 Audio/video, information and communication technology equipment — Part 1: Safety requirements Z32-09 Electrical safety and essential electrical systems in health care facilities CAN/CSA-Z305.8-03 (R2013) Medical supply units Z305.12-06 (R2012) Safe storage, handling, and use of portable oxygen systems in residential buildings and health care facilities Z305.13-09 Plume scavenging in surgical, diagnostic, therapeutic, and aesthetic settings CAN/CSA-Z5359-10 Low-pressure hose assemblies for use with medical gases CAN/CSA-Z9170-1-11 Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases, vacuum, and anaesthetic gas scavenging systems CAN/CSA-Z10524-1:12 Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices CAN/CSA-Z15002:12 Flow-metering devices for connection to terminal units of medical gas pipeline systems ASME (American Society of Mechanical Engineers) PTC 25-2008 Pressure Relief Devices CGA (Compressed Gas Association) V-1-2013 Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections V-5-2008 (reaffirmed 2013) Diameter Index Safety System (Noninterchangeable Low Pressure Connections for Medical Gas Applications)		

IEC60601_1U ATTACHMENT			
Clause	Requirement + Test	Result - Remark	Verdict
	ISO (International Organization for Standardization) 32:1977 Gas cylinders for medical use — Marking for identification of content 407:2004 Small medical gas cylinders — Pin-index yoke-type valve connections 9170-2:2008 Terminal units for medical gas pipeline systems — Part 2: Terminal units for anaesthetic gas scavenging systems		
3	Terminology and definitions		Pass
3.41	HIGH VOLTAGE		N/A
	[Replace this Clause in the Canadian deviations in the adopted Standard with the following] voltage above 1000 V ac for ac circuits or voltage above 1060 V dc for dc circuits, as defined in the Canadian Electrical Code, Part I		N/A
4	General requirements		Pass
4.1A	[Add the following clause] General requirements applicable to ME EQUIPMENT and ME SYSTEMS are provided in CAN/CSA C22.2 No. 0.		Pass
4.8	Components of ME EQUIPMENT		Pass
	[Replace Items a) and b) and Note 2 with the following]		Pass
	a) The applicable safety requirements of a relevant CSA Group, IEC, or ISO Standard; or		Pass
	b) where there is no relevant CSA Group, IEC, or ISO Standard, the requirements of this Standard shall be applied		Pass
	Note 2: If there are neither requirements in this Standard nor in a CSA Group, IEC, or ISO Standard, any other applicable source (e.g., standards for other types of devices, national standards) could be used to demonstrate compliance with the RISK MANAGEMENT PROCESS.		-
4.10.2	SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS		Pass
	[Replace the first sentence with the following] ME EQUIPMENT intended to be connected to SUPPLY MAINS shall be in accordance with the Canadian Electrical Code, Part I, and the following		Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	RATED voltages shall not be exceeded:		
7.	ME EQUIPMENT identification, marking and documents		Pass
9.2.3 [SCC]	CBs shall include dual language safety labeling within their product certification requirements, if so required by the standard or by the authority having jurisdiction.		N/A
	The manufacturer has confirmed they have the ability to include English and French safety labeling (markings associated with the signal words DANGER, WARNING, and CAUTION) when required.		N/A
	Manufacturer has a method to manage distribution of products, IF all products with the Canadian certification mark are NOT going to include the dual language.		N/A
7.5	Safety signs		N/A
	[Replace the paragraph starting with “When supplementary text” in IEC Amendment 1 with the following] When supplementary text is placed together with safety signs, the supplementary text shall be in English and French for the intended OPERATOR.		N/A
7.7	Colours of the insulation of conductors		Pass
7.7.1	PROTECTIVE EARTH CONDUCTOR		N/A
	[Replace Clause 7.7.1 in the adopted Standard with the following] A PROTECTIVE EARTH CONDUCTOR shall be identified throughout its length by green or green and yellow coloured insulation.		N/A
7.7.2	PROTECTIVE EARTH CONNECTIONS		N/A
	[Replace Clause 7.7.2 in the adopted Standard with the following] A PROTECTIVE EARTH CONDUCTOR or a PROTECTIVE EARTH CONNECTION of any insulation on conductors shall be identified by either green or green and yellow colours at least at the termination of the conductors.		N/A
7.7.3	Green or green and yellow insulation		Pass
	[Replace Clause 7.7.3 in the adopted Standard, as modified by IEC Amendment 1, with the following]		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Identification by green or green and yellow insulation shall only be used for:		N/A
	- PROTECTIVE EARTH CONDUCTORS (see Clause 8.6.2);		N/A
	- conductors as specified in Clause 7.7.2; Note: In other safety Standards such as CSA C22.2 No. 62368-1, internal connections between conductive parts and the main protective earth are called "protective bonding conductors".		N/A
	- POTENTIAL EQUALIZATION CONDUCTORS (see Clause 8.6.7);		N/A
	- FUNCTIONAL EARTH CONDUCTORS (see Clause 8.6.9).		Pass
7.7.4	Neutral conductor		Pass
	[Replace Clause 7.7.4 in the adopted Standard with the following] Colours of neutral conductors and POWER SUPPLY CORD conductors shall be in accordance with the Canadian Electrical Code, Part I, CSA C22.2 No. 21, and CSA C22.2 No. 49.		Pass
7.7.5	POWER SUPPLY CORD conductors		Pass
	[Replace Clause 7.7.5 in the adopted Standard with the following] Colours of conductors in POWER SUPPLY CORDS shall be in accordance with the Canadian Electrical Code, Part I, CSA C22.2 No. 21, and CSA C22.2 No. 49.		Pass
	Compliance with the requirements of Clause 7.7 is checked by inspection.		Pass
7.9	ACCOMPANYING DOCUMENTS		N/A
7.9.2.1	General		N/A
	[Replace the last paragraph in the adopted Standard with the following] The instructions for use shall be in English and French for the intended OPERATOR.		N/A
8	Protection against electrical HAZARDS from ME EQUIPMENT		Pass
8.6	Protective earthing, functional earthing and potential equalization of ME		Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	EQUIPMENT		
8.6.4	Impedance and current-carrying capability		N/A
	[Replace Clause 8.6.4 in the adopted Standard, as modified by IEC Amendments 1 and 2, with the following]		N/A
	PROTECTIVE EARTH CONNECTIONS shall be able to carry fault currents reliably and without excessive voltage drop.		N/A
	Impedance and current-carrying capability shall comply with CSA C22.2 No. 0.4.		N/A
	For PERMANENTLY INSTALLED ME EQUIPMENT and ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD, the impedance between the PROTECTIVE EARTH TERMINAL (inside the ME EQUIPMENT) and any part that is PROTECTIVELY EARTHED shall not exceed 100 mΩ. For ME EQUIPMENT with an APPLIANCE INLET, the impedance between the earth pin of the APPLIANCE INLET and any part that is PROTECTIVELY EARTHED shall not exceed 100 mΩ……..:		N/A
	In addition to the test above, for ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD or any DETACHABLE POWER SUPPLY CORD (supplied or specified by the MANUFACTURER), the impedance between the protective earth pin of the MAINS PLUG and the PROTECTIVE EARTH TERMINAL (inside the ME EQUIPMENT) shall not exceed 100 mΩ……..:		N/A
	Where an APPLIANCE INLET forms the supply connection to ME EQUIPMENT, the earth pin of the APPLIANCE INLET is regarded as the PROTECTIVE EARTH TERMINAL. The combined testing requirements above are equivalent to 200 mΩ impedance testing requirements as described in IEC 60601-1. Separate testing is required to comply with CSA C22.2 No. 0.4.		N/A
	Testing shall be carried out using a DETACHABLE POWER SUPPLY CORD as provided or specified (length and cross-sectional area as per the Canadian Electrical Code, Part I) by the MANUFACTURER.		N/A
	The test current shall have the following		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	characteristics: — for cord-connected equipment, twice the rating of the attachment plug cap, but not less than 40 A; — for equipment for permanent connection to the supply, twice the rating of the fuse that is required by the Canadian Electrical Code, Part I for the branch circuit to which the equipment is connected, up to 250 A; and — 500 A for equipment for permanent connection to the supply when a branch circuit fused at over 250 A is required.		
	Compliance is checked by the following test: — for test currents up to 500 A, the measured potential drop shall not exceed 4 V; — for equipment that requires branch circuit fusing over 250 A, the measured potential drop multiplied by the required fusing and divided by 250 shall not exceed 4 V; — there shall be no melting of any metal in the bond and no heating or burning that is likely to create a fire hazard; and — the time duration— the time duration for testing is indicated in Table 8.6.4A:		N/A
	Table 8.6.4A Time duration of impedance test current Fusing of branch circuit required for equipment (A) --> Time (min) 0-30 --> 2 31-60 --> 4 61-100 --> 6 101-200 --> 8 201 and over --> 10 Note: Additional information can be found in CSA C22.2 No. 0.4.		N/A
	Alternatively, dc may be used for this test, if the ME EQUIPMENT is rated dc.		N/A
	Note: When protective earth is relied on as a MEANS OF PROTECTION, the test current is determined based on the location where a fault could occur. If the prospective fault is in the mains supply circuit prior to the overcurrent protection included in the ME EQUIPMENT, the test current for that part of the protective earth circuit is based		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	on the rating of the external overcurrent protection included in the building infrastructure or specified in the ACCOMPANYING DOCUMENTS (two times the interrupt rating of the external overcurrent protection). If the prospective fault is in the mains supply circuit after the overcurrent protection included in the ME EQUIPMENT, the test current is based on the rating of the overcurrent protection included in the ME EQUIPMENT (two times the interrupt rating of the ME EQUIPMENT overcurrent protection). In either case, the minimum test current is 40 A. The voltage drop between the parts described is measured and the impedance determined from the current and voltage drop. If the measured impedance is within the permitted limit, either the impedance measurement is then repeated using a current source with a no-load voltage sufficient to deliver the specified current into the total impedance, or the current-carrying ability of the relevant protective earth conductor and protective earth connection is confirmed by checking that their cross-sectional area is at least equal to that of the relevant current-carrying conductors.		
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS		Pass
8.7.3	Allowable values		Pass
	[Add the following paragraph] Allowable values shall be in accordance with the Canadian Electrical Code, Part I.		Pass
8.11	MAINS PARTS, components and layout		N/A
8.11.3.2	Types		Pass
	[Replace this clause with the following]		Pass
	The following requirements for POWER SUPPLY CORDS shall apply:		Pass
	a) The MAINS PLUG of non-PERMANENTLY INSTALLED EQUIPMENT shall be:		Pass
	i) if moulded-on type, a hospital-grade mains plug complying with CSA C22.2 No. 21;	Component, to be evaluated in end-product	N/A
	ii) a hospital-grade disassembly attachment plug type complying with CSA C22.2 No. 42; or	Component, to be evaluated in end-product	N/A
	iii) Class II equipment having fuses on the line	two fuses used.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	side(s), and the neutral may use a non-polarized attachment plug or a polarized attachment plug. CSA configuration type 1-15P shall be required and meets all applicable requirements in CSA C22.2 No. 21 and CSA C22.2 No. 42. Where a polarized attachment plug is used, the power supply cord is connected to the wiring of the equipment on the ungrounded side of the line when any of the following devices are used in the primary circuit:		
	1) the centre contact of an Edison base lampholder;		N/A
	2) a single pole switch;		N/A
	3) an automatic control with a marked off position;		N/A
	4) a solitary fuse/fuse holder; or		N/A
	5) any other single pole overcurrent protective device.		Pass
	b) A detachable power supply cord for non-permanently installed equipment (cord-connected equipment) shall be of a type:		Pass
	i) that can be shown to be unlikely to become detached accidentally, unless it can be shown that detachment will not constitute a safety hazard to a patient or operator;		Pass
	ii) for which it can be shown that the impedance of the earth (ground) circuit contacts will not constitute a safety hazard to a patient or operator; and		N/A
	iii) that has a terminal configuration or other constructional feature that will minimize the possibility of its replacement by a detachable power supply cord which could create a hazardous situation.		N/A
	c) The detachable power supply cord shall:		Pass
	i) comply with the applicable requirements of CSA C22.2 No. 21; and		Pass
	ii) not be smaller than No. 18 AWG, and the mechanical serviceability is not less than:	Min. 18AWG	Pass
	1) Type SJ or equivalent for ME EQUIPMENT that is mobile or exposed to abuse; and	Component, to be evaluated in end-product	N/A
	2) Type SV or equivalent for ME EQUIPMENT that is not exposed to abuse (or Type HPN if required because of temperature). Note: See CSA C22.2 No. 49 for requirements for the cord types mentioned in Sub-item 2).		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	d) Installation of POWER SUPPLY CORDS shall meet the requirements of the Canadian Electrical Code, Part I, as applicable.		Pass
	[Add the following to this Canadian deviation in the adopted Standard] The POWER SUPPLY CORD used with the ME EQUIPMENT shall be in accordance with the temperature rating to which it has been RATED. Note 1DV: Refer to the Canadian Electrical Code, Part I, Tables 11 and 12 for additional information.	Component, to be evaluated in end-product	N/A
	Compliance is checked by inspection and measurement……..:	See appended table 8.10	Pass
8.11.3.3	Cross-sectional area of POWER SUPPLY CORD conductors		Pass
	[Replace Clause 8.11.3.3 in the adopted Standard, as modified by Amendment 2, with the following] The NOMINAL cross-sectional area of conductors of any POWER SUPPLY CORD of ME EQUIPMENT shall be not less than the requirements of the Canadian Electrical Code, Part I, and CSA C22.2 No. 21. Note: Table 17 can be used for European countries or other countries where the nominal cross-sectional area is measured in mm2 (HAR); American Wire Gauge (AWG) is the nominal cross-sectional area used in Canada as per the Canadian Electrical Code, Part I.		Pass
	Compliance is checked by inspection……..:	See appended Table 8.10	Pass
8.11.5	Mains fuses and OVER-CURRENT RELEASES		Pass
	[Replace Clause 8.11.5 in the Canadian deviations in the adopted Standard with the following] Installation of overcurrent protective devices shall be in accordance with the Canadian Electrical Code, Part I		Pass
9	Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS		Pass
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure		N/A
9.7.5	Pressure vessels		N/A
	[Replace this clause with the following]		N/A

IEC60601_1U ATTACHMENT			
Clause	Requirement + Test	Result - Remark	Verdict
	Pressure vessels shall comply with the requirements of CSA B51, as applicable		
9.7.7	Pressure-relief device		N/A
	[Add the following as the first paragraph of this Clause] A pressure-relief device shall comply, as applicable, with the requirements of ASME PTC 25 or equivalent Canadian requirements.		N/A
13	HAZARDOUS SITUATIONS and fault conditions		Pass
13.2	SINGLE FAULT CONDITIONS		Pass
13.2.9	Interruption and short circuiting of motor capacitors		N/A
	[Replace the second paragraph of the compliance statement in the adopted Standard with the following] The test with a short-circuited capacitor is not performed if the motor is provided with a capacitor that complies with IEC 60252-1 or is included as part of the evaluation of the motor in accordance with CSA C22.2 No. 100, and the ME EQUIPMENT is not intended for unattended use (including automatic or remote control).		N/A
	For additional test criteria, see Clause 13.2.10.		N/A
15	Construction of ME EQUIPMENT		Pass
15.4	ME EQUIPMENT components and general assembly		Pass
15.4.1	Construction of connectors		N/A
	[Add the following item]		N/A
	bA) The point of connection of gas cylinders to ME EQUIPMENT is gas-specific and clearly identified so that errors are avoided when a replacement is made. Medical gas inlet connectors on ME EQUIPMENT shall be:		N/A
	i) gas-specific, yoke type, or nut and nipple type valve connections complying with CGA V-1 for pressures over 1380 kPa (200 psi); or		N/A
	ii) DISS type complying with CGA V-5 for pressures 1380 kPa (200 psi) or less and configured to permit the supply of medical gases from low-pressure connecting assemblies complying with CAN/CSA Z5359		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Note: Users of this Standard should consult the CSA Z305 series of Standards, CAN/CSA-Z9170-1, ISO 9170-2, CAN/CSA-Z10524, and CAN/CSA-Z15002 for further information regarding inlet connectors; ISO 407 for requirements addressing yoke type valve connections; and ISO 32 for colour coding.		-
15.4.8	Internal wiring of ME EQUIPMENT		N/A
	[Replace this Clause with the following]		N/A
	Internal wiring of ME EQUIPMENT shall be in accordance with the Canadian Electrical Code, Part I.		N/A
	Except for flexible cord, equipment wire, control circuit insulated conductors, and cable, insulated conductors shall be not smaller than No. 14 AWG when made of copper and not smaller than No. 12 AWG when made of aluminium. Note 1: See the Canadian Electrical Code, Part I, Rule 4-002.		N/A
	The maximum current that an equipment wire of a given size may carry shall be as specified in Table 12 of the Canadian Electrical Code, Part I. Note 2: For additional information refer to the Canadian Electrical Code, Part I, Rule 4-014.		N/A
15.5	MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5		Pass
15.5.1.3	Overload test		Pass
	[Replace the second and third dashed items of Item b) of Clause 15.5.1.3 in the adopted Standard with the following]		N/A
	- Fuses not in accordance with IEC 60127-1 but in accordance with the CSA C22.2 No. 248 series of Standards: 30 min at the current according to the characteristics supplied by the fuse manufacturer, specifically the 30 min clearing-time current. If no 30 min clearing-time current data is available, the test current from Table 32 is used until THERMAL STABILITY is achieved.		N/A
	- Other protective device as per the Canadian Electrical Code, Part I: until THERMAL STABILITY at a current just below that which caused the device to operate in Item a).		Pass
	This portion of the overload test is concluded at the		Pass

IEC60601_1U ATTACHMENT			
Clause	Requirement + Test	Result - Remark	Verdict
	specified time or when a second protective device opens.		
16	ME SYSTEMS		N/A
16.1	General requirements for the ME SYSTEMS		N/A
	[Replace the paragraph that starts with “An ME SYSTEM shall provide:” with the following]		N/A
	An ME SYSTEM shall be provided:		N/A
	- within the PATIENT ENVIRONMENT, the level of safety equivalent to ME EQUIPMENT complying with this CSA Group Standard; and		N/A
	- outside the PATIENT ENVIRONMENT, the level of safety equivalent to equipment complying with their respective CSA Group, IEC, or ISO safety Standards.		N/A
	[Replace the third-last paragraph with the following] Non-ME EQUIPMENT, when used in an ME SYSTEM, shall comply with the CSA Group, IEC, or ISO safety Standards that are relevant to that equipment.		N/A
16.9	ME SYSTEM connections and wiring		N/A
16.9.2.1	MULTIPLE SOCKET-OUTLET		N/A
	[Replace the first sentence of Item c) of Clause 16.9.2.1 in the adopted Standard with the following]		N/A
	c) The MULTIPLE SOCKET-OUTLET shall comply with CSA C22.2 No. 308 as applicable and the following requirements.		N/A
	[Add the following note to Item d) in the Canadian deviations in the adopted Standard]		N/A
	d) If the MULTIPLE SOCKET OUTLET is combined with a separating transformer, the following additional requirements shall apply:		N/A
	The separating transformer complies with this Standard.		N/A
	Alternatively, the separating transformer may comply with the requirements of CAN/CSA-E61558-2-1, except that the requirements of maximum RATED output power of 1 kVA and degree of protection IPX4 do not apply.		N/A
	Note 1: As a separating transformer is not a MAINS SUPPLY TRANSFORMER, it does not require more than BASIC INSULATION.		N/A

IEC60601_1U ATTACHMENT			
Clause	Requirement + Test	Result - Remark	Verdict
	Note 2: Limitation of output power is not explained in CAN/CSA-E61558-2-1 and the RATED output power is defined by the fuse in the installation and by the allowable power supply cable used. However, the characteristics of the separating transformer need to be carefully selected, taking into account the variations in the load current of the ME SYSTEM to ensure that the voltage supplied to the various items of the ME SYSTEM remains within the limits specified for the equipment. Note 3: For additional details refer to the Canadian Electrical Code, Part I, Diagrams 1 and 2.		
	The separating transformer assembly shall be a CLASS I construction.		N/A
	The degree of protection against ingress of water as given in IEC 60529 is specified.		N/A
	The separating transformer assembly shall be marked according to the requirements of 7.2 and 7.3.		N/A
	The MULTIPLE SOCKET OUTLET is permanently connected to the separating transformer or,		N/A
	The socket-outlet of the separating transformer assembly shall be of a type that cannot accept MAINS PLUGS of any of the kinds identified in Canadian Electrical Code, Part I (see Figure I.1 and Figure I.2 of this Standard)		N/A
	[Add the following item] dA) The MULTIPLE SOCKET OUTLET complies with the requirements of CSA C22.2 No. 42, CSA C22.2 No. 49, and Item d) of this Standard, as applicable.		N/A

---------- END OF ATTACHMENTS ----------