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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. ..... :	**2407B2585SHA-003**
Date of issue ..... :	**2024-09-15**
Total number of pages ..... :	**31**
Name of Testing Laboratory preparing the Report ..... :	Intertek Testing Services (Shanghai FTZ) Co., Ltd. Building No. 86, 1198 Qinzhou Road (North) Shanghai 200233 China
Applicant's name ..... :	GlobTek, Inc.
Address ..... :	186 Veterans Drive Northvale NJ 07647, USA
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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Test item description ..... :	Medical Power Supply
Trade Mark(s) ..... :	GlobTek, Inc.
Manufacturer ..... :	GlobTek, Inc. 186 Veterans Drive Northvale NJ 07647, USA
Model/Type reference ..... :	GT*46402-*** (Refer to page 7 for details.)
Ratings ..... :	Input: 100-240V~, 50-60Hz, 1.0A Output :5-48Vdc, Max6A, Max. 40W.

Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):

☒	**CB Testing Laboratory:**	Intertek Testing Services (Shanghai FTZ) Co., Ltd.	
Testing location/ address.....:		Building No. 86, 1198 Qinzhou Road (North) Shanghai 200233 China	
Tested by (name, function, signature).....:		Vivian Xu (Engineer)	Vivian Xu
Approved by (name, function, signature)...:		Larry Zhong (Mandated reviewer)	Larry Zhong
☐	**Testing procedure: CTF Stage 1:**	N/A	
Testing location/ address.....:			
Tested by (name, function, signature).....:			
Approved by (name, function, signature)...:			
☐	**Testing procedure: CTF Stage 2:**	N/A	
Testing location/ address.....:			
Tested by (name + signature).....:			
Witnessed by (name, function, signature) .:			
Approved by (name, function, signature)...:			
☐	**Testing procedure: CTF Stage 3:**	N/A	
☐	**Testing procedure: CTF Stage 4:**	N/A	
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):

None

Summary of testing:

Tests performed (name of test and test clause):	**Testing location:**
4.2.2 Environmental condition test of transport and storage between uses 4.2.3.1 Environmental operating condition test 10.1.2 a) Shock test 10.1.2 b) Vibration test The sample tested complies with the requirements of IEC 60601-1-11:2020.	Intertek Testing Services (Shanghai FTZ) Co., Ltd. Building No. 86, 1198 Qinzhou Road (North) Shanghai 200233 China

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

None.

☒ **The product fulfils the requirements of** IEC 60601-1-11:2015/AMD1:2020

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").

GMS-QC-12 Estimation of Measurement Uncertainty, 07-November-2023 Initial Release.

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

Information on uncertainty of measurement:

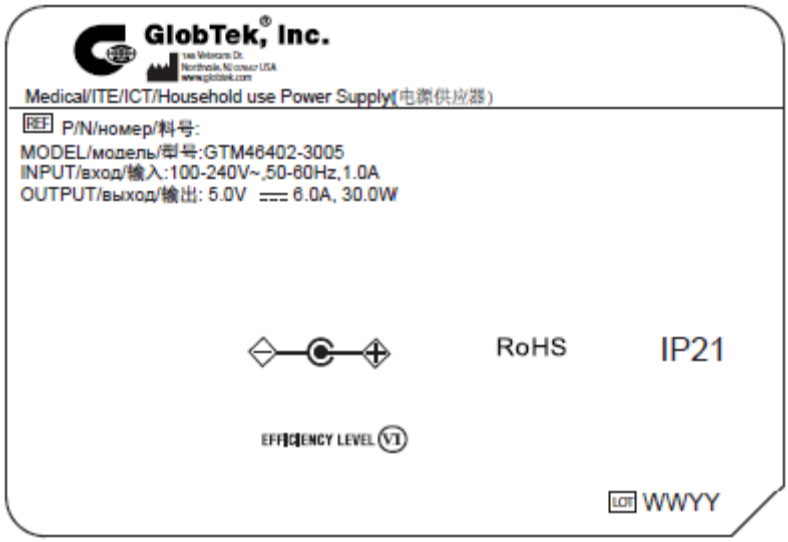
The uncertainties of measurement are calculated by the laboratory based on application of criteria given by OD-5014 for test equipment and application of test methods, decision sheets and operational procedures of IECEE.

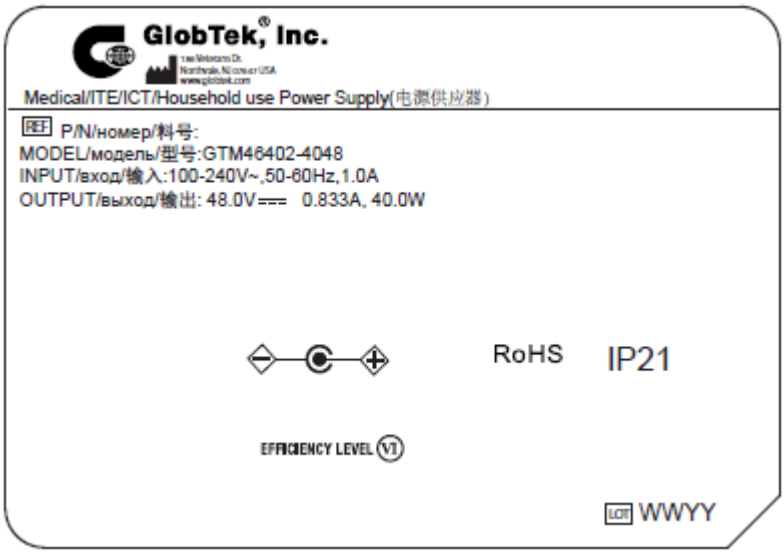
IEC Guide 115 provides guidance on the application of measurement uncertainty principles and applying the decision rule when reporting test results within IECEE scheme, noting that the reporting of the measurement uncertainty for measurements is not necessary unless required by the test standard or customer.

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

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.





Note:
The above markings are the minimum requirements required by the safety standard. For the final production samples, the additional markings which do not give rise to misunderstanding may be added.
Other models are with similar label as corresponding above models except different model name and output ratings.
When the equipment is vended to EU, the name and address of the importer or authorized representative within the EEA shall be added on the equipment;

Test item particulars.....:	
Classification of installation and use.....:	Direct plug-in for power adapter model.
Supply Connection.....:	Direct plug-in
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 .....:	2024-07-30
Date (s) of performance of tests.....:	2024-07-30 to 2024-08-30

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 60601-1-11:2015 Standard dated 2015-12-25.**

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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) ..... :	Factory 1 GlobTek, Inc. 186 Veterans Drive Northvale NJ 07647, USA Factory 2 GlobTek (Suzhou) Co., Ltd Building 4, No. 76, Jin Ling East Rd., Suzhou Industrial Park, Suzhou, JiangSu 215021, China

General product information and other remarks:

Product covered by this report is medical power supply module, which can be used as a part of medical equipment.

Transformers used in all models are the same construction. The turns of secondary winding may be added or reduced according different output voltage. All models have same PCB, but some non-critical components may be adjusted according to different output voltage. The parameters of these components depend on output voltage.

All the types are designed for continuous operation and no applied part is defined.

The insulation construction of EUT is evaluated as 2MOPP in this report as customer's request.

Model Similarity:

GT*46402-***

The 1st "*" can be "M" or "-"or "H" for market identification and not related to safety.

The 2nd "*" can be "01" to "40", with interval of 1W, denotes the rated output wattage designation.

The 3rd "*" can be "05" to "48", or "5.0" to "48.0" with interval of 0.1V, denotes the standard rated output voltage designation.

The last "*" denotes any six character, which can be 0-9 or A-Z or () or [ ] or – or blank for marketing purposes.

Technical Considerations:

Models GTM46402-4048, GTM46402-3005 are tested as typical models.
The products are not intended to use in environment which altitude exceed 3000m.

Scope of Power Supply evaluation defers the following clauses to be determined as part of the end product investigation:
Clause 7.5 (Safety Signs),
Clause 7.9 (Accompanying Documents are provided for some critical issue like technical data, safety warnings, necessary information to set up, but further evaluation is needed on end product level.),
Clause 8.11.5 (Mains Fuse with High Breaking Capacity),
Clause 9 (ME Hazard), except 9.1 and 9.3 are evaluated,
Clause 10 (Radiation),
Clause 11.7 (Biocompatibility),
Clause 14 (PEMS),
Clause 16 (ME Systems),
Clause 17 (EMC)

Determination of the test conclusion is based on IEC Guide 115 in consideration of measurement uncertainty.

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Clause	Requirement + Test	Result - Remark	Verdict

4	**GENERAL REQUIREMENTS**		P
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:		P
	– 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) .....:	See the IEC 60601-1 report 2407B2585SHA -001	—
	– 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 for life- supporting me equipment.	—
	- 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	No such condition	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	No such condition	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	No such condition	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	No such condition	N/A
4.2.2	**Environmental conditions of transport and storage between uses, indicated in instructions for use**		P
	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		P
	temperature range:-25 °C to + 5 °C		P
	temperature range:+5 °C to +35 °C at a non-condensing relative humidity up to 90 %		P
	temperature range: >35 °C to 70 °C at a water vapour pressure up to 50 hPa		P
	For more restricted range of environmental transport and storage conditions between uses, the environmental conditions are specified	See RM table 4.2.2	P
	– Justified in the RISK MANAGEMENT FILE		P

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Clause	Requirement + Test	Result - Remark	Verdict
	– 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		P
	a) ME EQUIPMENT prepared for transportation or storage according to instructions for use		P
	b) ME EQUIPMENT exposed to its lowest specified environmental transport and storage conditions (temperature $^{0}_{-4}$ °C) (°C).....:	-10 °C	P
	– For at least 16 h or, ensure ME EQUIPMENT reached THERMAL STABILITY for at least 2 h	16h	P
	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 and 90% relative humidity	P
	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, ± %).....:	70 °C, 50hpa	P
	– For at least 16 h or, ensured ME EQUIPMENT reached THERMAL STABILITY for at least 2 h		P
	e) At the end of this conditioning period, ME EQUIPMENT allowed to return and stabilize at the operating conditions of NORMAL USE		P

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Clause	Requirement + Test	Result - Remark	Verdict
	f) ME EQUIPMENT evaluated to its specifications and ensured it provides BASIC SAFETY and ESSENTIAL PERFORMANCE		P
4.2.3.1	**Environmental operating conditions - Continuous operating conditions**		**P**
	Instructions for use indicated permissible environmental operating conditions of the ME EQUIPMENT		P
	ME EQUIPMENT complied with its specifications and all requirements of the standard when operated in NORMAL USE within temperature + 5 °C to +40 °C,		N/A
	Relative humidity range of 15 % to 90%, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa; and		N/A
	An atmospheric pressure range of 700 hPa to 1060 hPa		N/A
	For more restricted range of environmental operating conditions	0 °C to +40 °C	P
	- justified in the risk management file;	See RISK MANAGEMENT Table 4.2.3.1	P
	-marked on the equipment; or were nor practical in the instructions for use……..:	be disclosed in the instructions for use	P
	– Marked on the carrying case when the instructions for use indicate the ME EQUIPMENT is intended to be operated in a carrying case	No 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	No such symbol	N/A
	Symbol 5.3.8 (ISO 7000-2620) of ISO 15223-1:2016 used to mark humidity range	No such symbol	N/A
	Symbol 5.3.9 (ISO 7000-2621) of ISO 15223-1:2016 used to mark atmospheric pressure range	No such symbol	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		P
	a) ME EQUIPMENT was set up for operation according to INTENDED USE		P
	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, 6h	P
	c) ME EQUIPMENT evaluated to its specifications and ensured it continued to provide BASIC SAFETY and ESSENTIAL PERFORMANCE		P

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Clause	Requirement + Test	Result - Remark	Verdict
	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.		P
	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.		P
	f) Pressure in chamber relieved		P
	g) ME EQUIPMENT cooled to its lowest specified environmental operating conditions		P
	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 .....:	6h	P
	i) ME EQUIPMENT met its specifications and BASIC SAFETY and ESSENTIAL PERFORMANCE		P
	j) ME EQUIPMENT warmed to its highest specified continuous environmental operating conditions		P
	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 .....:	6h	P
	l) ME EQUIPMENT met its specifications and BASIC SAFETY and ESSENTIAL PERFORMANCE		P
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).	Not Transit-operable equipment	N/A

5	**GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT**		P
	In addition to the requirements of 5.9.2.1 of with IEC 60601-1 standard, accessibility determined as indicated below:		P
	ACCESSIBLE parts of ME EQUIPMENT identified by inspection and, when necessary, by testing		P
	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:		P
	– for all positions of the ME EQUIPMENT operating in NORMAL USE	No opening	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– after opening ACCESS COVERS and removal of parts, including lamps, fuses, and fuse holders when:		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**		P
	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:	Class II	P
	– CLASS II or INTERNALLY POWERED .....:	Class II	P
	– Not provided with a FUNCTIONAL EARTH TERMINAL		P
	– When equipped with APPLIED PARTS, they are TYPE BF or CF .....:	No applied parts	N/A
7	**ME EQUIPMENT IDENTIFICATION, MARKING AND DOCUMENTS**		P
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	2407B2585SHA -002 and usability engineering should be considered in end product again.	N/A
	ME EQUIPMENT and ME SYSTEMS intended for HOME HEALTHCARE ENVIRONMENT are simple to use and do not require referencing complex ACCOMPANYING DOCUMENTS.....:		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 .. :	IP20	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) ..... :		N/A
	b) the carrying case marked with its degree of protection.....:		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		P

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Clause	Requirement + Test	Result - Remark	Verdict
7.3.1	ACCOMPANYING DOCUMENTS indicate the LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION contact the MANUFACTURER or MANUFACTURER'S representative on the following issues:	Accompany documents are provided for some critical issue like technical data, safety warnings, necessary information to set up	P
	– Assistance in setting up, using, or maintaining the ME EQUIPMENT or ME SYSTEM when needed, or		P
	– To report unexpected operation or events		P
	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		P
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:	Accompany documents are provided for some critical issue like technical data, safety warnings, necessary information to set up	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**		P
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 ..... :	See RM table 7.4.1	P
	The instructions for use address the following issues, as applicable:		N/A
	– 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

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Clause	Requirement + Test	Result - Remark	Verdict
	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:	No internal electrical power source	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)	Necessary information to set up was provided in the instruction.	P
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)	No connection to PATIENT	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) ..... :	No such feature.	N/A
	-the time required for ME EQUIPMENT to warm from the minimum storage temperature between uses until it is ready for intended use; and ..... :	No such conditions	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 ..... :	No such conditions	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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	See RM table 7.4.5	P
	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	No need of such guide for power supply. But final determination in the 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:	No cleaning, disinfection and sterilization required for power supply. But final determination in the end product.	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
	– 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

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Clause	Requirement + Test	Result - Remark	Verdict
	– 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:		P
	– EXPECTED SERVICE LIFE of the ME EQUIPMENT .....:	5 years	P
	– EXPECTED SERVICE LIFE of parts and ACCESSORIES shipped with the ME EQUIPMENT .....:	5 years	P
	– SHELF LIFE of parts and ACCESSORIES shipped with ME EQUIPMENT when SHELF LIFE is less than the EXPECTED SERVICE LIFE .....:	No such parts	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	Not applicable for power supply	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	Not applicable for power supply	N/A
7.5	**Technical description**		N/A
7.5.1	The technical description for PERMANENTLY INSTALLED CLASS I ME EQUIPMENT includes:	Not permanently installed	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
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):	No cleaning, disinfection and sterilization required for power supply.	N/A
	– Before and after any type of service PROCEDURE		N/A
	– When the ME EQUIPMENT is transferred to another PATIENT		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
8	**PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS**		N/A
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)	No cleaning, disinfection and sterilization required for power supply	N/A
	USABILITY of each such PROCESS pertaining to a LAY OPERATOR was investigated by the USABILITY ENGINEERING PROCESS .....:		N/A
8.2	A LAY OPERATOR in the HOME HEALTHCARE ENVIRONMENT can perform the cleaning and sterilization PROCESSES when intended (see 7.4.7)	No sterilization required for power supply.	N/A
	USABILITY of each such PROCESS pertaining to a LAY OPERATOR was investigated by the USABILITY ENGINEERING PROCESS		N/A
8.3	**Additional requirements for ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS**		P
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 .....:		N/A
	All other ME EQUIPMENT maintained BASIC SAFETY and ESSENTIAL PERFORMANCE after undergoing the test of IEC 60529 for at least IP21.....:	IP21	P
	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		P
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		P
	Tests of IEC 60529:1989 conducted with the equipment placed in the least favourable position of NORMAL USE and the ENCLOSURES inspected		P
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		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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 .....:		N/A
	Optionally, independent means were used to provide 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 .....:		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
	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 .....:		N/A
8.5	**Additional requirements for an INTERNAL ELECTRICAL POWER SOURCE**		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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 internal electrical power source	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	No internal power	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.		N/A
9	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		N/A
	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:		N/A
	– changes of controls		N/A
	– unexpected movement		N/A
	– potential for misconnection		N/A
	– potential for improper operation, or unsafe use		N/A
	– potential for confusion as to current operational mode		N/A
	– change in the transfer of energy or substance		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	- exposure to environmental conditions specified in this standard		N/A
	– 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.		N/A
	The MANUFACTURER'S USABILITY ENGINEERING PROCESS included the least capable intended LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION		N/A
	USABILITY ENGINEERING FILE inspected for compliance .....:		N/A
10	**CONSTRUCTION OF ME EQUIPMENT**		P
10.1	Additional requirements for mechanical strength		P
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	Non-transit-operable	P
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)		P
	ME EQUIPMENT maintained BASIC SAFETY and ESSENTIAL PERFORMANCE after mechanical tests		P
	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		P
	a) Shock tests conducted in accordance with IEC 60068-2-27:2008 ..... :	See Appended Table 10.1.2a	P
	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	P
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	Not transit-operable me equipment	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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..... :		N/A
	2) Test type: Type 2..... :		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..... :		N/A
	2) Test type: Type 2..... :		N/A
	c) Broad-band random vibration test conducted on ME EQUIPMENT, parts, and mounting ACCESSORIES in accordance with IEC 60068-2-64:2008 ..... :		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 ..... :		N/A
	BASIC SAFETY and ESSENTIAL PERFORMANCE were maintained		N/A
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

11	**PROTECTION AGAINST STRANGULATION OR ASPHYXIATION**		P
	Means provided to control the RISK of strangulation and asphyxiation of the PATIENT and others to an acceptable level		P
	EQUIPMENT and RISK MANAGEMENT FILE inspected .... :	See RM table 11	P

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 applicable to component power supply system	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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 ..... :		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

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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**		**P**
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
5.3	Risk Management Report GT-RM2017-003 6.1	Operational hazard is identified	P
5.4	Risk Management Report GT-RM2017-003 6.2	The severity of the harm has been estimated as "3" The probability of occurrence of the harm has been estimated in "1"	P
5.5	Risk Management Report GT-RM2017-003 6.4	Intended use is identified	P

4.2.3.1	**RM RESULTS TABLE: Environmental operating conditions - Continuous operating conditions**		P
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
4.2	Risk management procedure GTQPR05000 A2 5.0	Intended use is identified	P
4.3	Risk management procedure GTQPR05000 A2 5.0	Hazardous situation is identified	P
4.4	Risk management procedure GTQPR05000 A2 5.0	Severity and probability is identified	P

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	--	Intended use is identified	N/A
5.3	Risk Management Report GT-RM2017-003 6.1	Operational hazard is identified	P
5.4	Risk Management Report GT-RM2017-003 6.2	The severity of the harm has been estimated as "2" The probability of occurrence of the harm has been estimated in "1"	P
5.5	Risk Management Report GT-RM2017-003 6.4	The risk is evaluated as "ACC'	P
6	Risk Management Report GT-RM2017-003 7	Intended use is identified	P
7.1	Risk Management Report GT-RM2017-003 8.1	The risk is evaluated as "ACC'	P

7.4.5	**RM RESULTS TABLE: : Additional requirements for operating instructions**	**P**

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Clause	Requirement + Test	Result - Remark	Verdict

Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
5.4	Risk Management Report GT-RM2017-003 6.2	Intended use is identified	P
5.5	Risk Management Report GT-RM2017-003 6.4	Operational hazard is identified	P
6	Risk Management Report GT-RM2017-003 7	The severity of the harm has been estimated as "2" The probability of occurrence of the harm has been estimated in "1"	P
7.1	Risk Management Report GT-RM2017-003 8.1	The risk is evaluated as "ACC'	P

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			

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Clause	Requirement + Test	Result - Remark	Verdict

10.1.2a	**TABLE: Shock test (IEC 60068-2-27:2008), using the following conditions*:**		**P**
	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**
Positive	X axis[2]	Yes	The enclosure shows no cracks and there is no damaged or loosing part inside the product after test. The EUT worked as normal and passed the dielectric strength test.
Negative	X axis[2]	Yes	
Positive	Y axis[2]	Yes	
Negative	Y axis[2]	Yes	
Positive	Z axis[2]	Yes	
Negative	Z axis[2]	Yes	
Supplementary information: ***(NOTE 1 This represents Class 7M1 as described in IEC TR 60721-4-7:2001 [6])			

10.1.2b	**TABLE: Broad-band random vibration test (IEC 60068-2-64:2008) using the following conditions*:**		**P**
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	Yes	The enclosure shows no cracks and there is no damaged or loosing part inside the product after test. The EUT worked as normal and passed the dielectric strength test.
2	1	Yes	
3	1	Yes	
1	2	Yes	
2	2	Yes	
3	2	Yes	
1	3	Yes	
2	3	Yes	
3	3	Yes	

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Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information:

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

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])

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:			

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/s^2 (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)			

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:

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)

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**		**P**
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
5.4	Risk Management Report GT-RM2017-003 6.2	Intended use is identified	
5.5	Risk Management Report GT-RM2017-003 6.4	Operational hazard is identified	
6	Risk Management Report GT-RM2017-003 7	The severity of the harm has been estimated as "2" The probability of occurrence of the harm has been estimated in "1"	
7.1	Risk Management Report GT-RM2017-003 8.1	The risk is evaluated as "ACC'	
7.2	Risk Management Report GT-RM2017-003 8.1	specifications control is identified	
7.3	Risk Management Report GT-RM2017-003 8.2	Product specification	

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

11.0	**RM RESULTS TABLE: PROTECTION AGAINST STRANGULATION AND ASPHYXIATION**		**P**
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
7.4	Risk Management Report GT-RM2017-003 8.3	The residual risk is evaluated as 'ACC'	
Supplementary information:			