Test Report issued under the responsibility of:

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..... :	**2407B2585SHA-002**
Date of issue ..... :	**2024-09-15**
Total number of pages ..... :	**17**
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 60601-1-6:2010, 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

Copyright © 2023 IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE System). All rights reserved.

This publication may be reproduced in whole or in part for non-commercial purposes as long as the IECEE is acknowledged as copyright owner and source of the material. IECEE takes no responsibility for and will not assume liability for damages resulting from the reader's interpretation of the reproduced material due to its placement and context.

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.

Test item description ..... :	Medical Power Supply
Trademark(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):
ANNEX I – IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist (Pages: 11)

Summary of testing:

Tests performed (name of test, test clause and date test performed):	**Testing location: (CBTL, SPTL, CTF, Subcontractor)**
Process standard only, no testing	N/A

Summary of compliance with National Differences (List of countries addressed):
None

☒ **The product fulfils the requirements of** IEC 60601-1-6:2010, AMD1:2013, AMD2:2020

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").

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

Procedure number, issue date and title:

GMS-QC-12 Estimation of Measurement Uncertainty, 07-November2023 Initial Release.

Information on uncertainty of measurement:

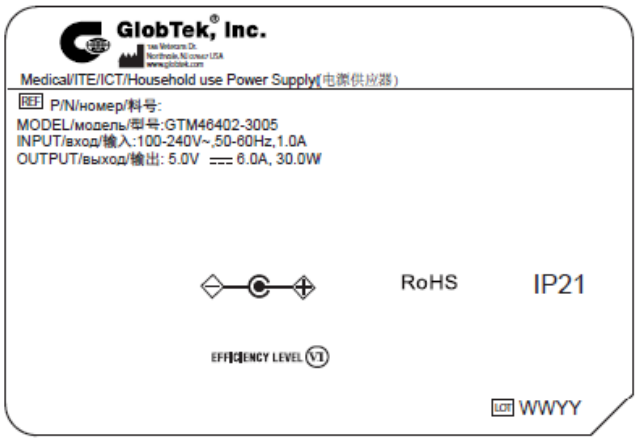
The uncertainties of measurement are calculated by the laboratory based on application of criteria given by OD-5014 for test equipment and application of test methods, decision sheets and operational procedures of IECEE.

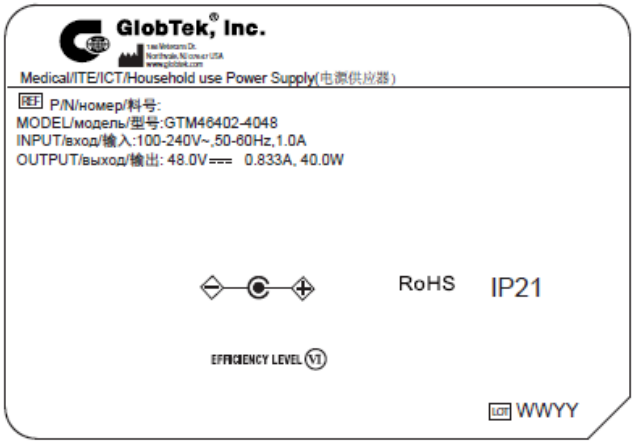
IEC Guide 115 provides guidance on the application of measurement uncertainty principles and applying the decision rule when reporting test results within IECEE scheme, noting that the reporting of the measurement uncertainty for measurements is not necessary unless required by the test standard or customer.

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.....:	No test need
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.

This report is for the exclusive use of Intertek's Client and is provided pursuant to the agreement between Intertek and its Client. Intertek's responsibility and liability are limited to the terms and conditions of the agreement. Intertek assumes no liability to any party, other than to the Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this report. Only the Client is authorized to permit copying or distribution of this report and then only in its entirety. Any use of the Intertek name or one of its marks for the sale or advertisement of the tested material, product or service must first be approved in writing by Intertek. The observations and test results in this report are relevant only to the sample tested. This report by itself does not imply that the material, product, or service is or has ever been under an Intertek certification program.

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.

IEC 60601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
4	**GENERAL REQUIREMENTS**		P
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	P
	Inspection of the USABILITY ENGINEERING FILE verified that the MANUFACTURER demonstrated compliance with IEC 62366-1:2015+A1:2020.	See QF-GT-DJD-7.3.2-20 Usability Engineering File P5/1.15	P
5	**ME EQUIPMENT ACCOMPANYING DOCUMENTS**		P
	The instructions for use shall contain a summary of the USE SPECIFICATION as specified in IEC 62366-1:2015, AMD1:2020, Clause 5.1	Refer to “power supply information” and “electrical specification” of SPEC	P
	The same information is also included in the technical description, if this is provided as a separate document from instructions for use	Not separately provided	N/A

ANNEX I - IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist			
Clause	Requirement + Test	Result - Remark	Verdict

4	**PRINCIPLES**		P
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	QF-GT-DJD-7.3.2-20 Usability QF-GT-DJD-7.3.2-20 Usability Engineering File	P
	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.		
	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.		
	Compliance with this subclause to exist when the requirements of this International Standard have been fulfilled.		
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):	QF-GT-DJD-7.3.2-20 Usability Engineering File	P
	a) inherently safe design and manufacture;		
	b) protective measures in the MEDICAL DEVICE itself or in the manufacturing PROCESS; and		
	c) information for SAFETY and, where appropriate, training to USERS.		
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	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 5 section1.15	P
4.2	The results of the USABILITY ENGINEERING PROCESS are stored in the USABILITY ENGINEERING FILE .....:	QF-GT-DJD-7.3.2-20 Usability Engineering File	P
4.3	The level of effort and the choice of methods and tools used to perform the USABILITY ENGINEERING PROCESS vary based on:	Document Reference No. in usability engineering file: QF-GT-DJD-7.3.2-20 Usability Engineering File Page 8, section 6	P
	a) the size and COMPLEXITY of the USER INTERFACE		
	b) the SEVERITY of the HARM associated with the use of the MEDICAL DEVICE		
	c) the extent or complexity of the USE SPECIFICATION		

ANNEX I - IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist			
Clause	Requirement + Test	Result - Remark	Verdict
	d) the presence of USER INTERFACE OF UNKNOWN PROVENANCE		
	e) the extent of the modification to an existing MEDICAL DEVICE USER INTERFACE that had been subjected to the USABILITY ENGINEERING PROCESS		
5	**USABILITY ENGINEERING PROCESS**		P
5.1	The MANUFACTURER shall prepare a USE SPECIFCATION. The USE SPECIFICATION shall include the following.....:	Document Reference No. in usability engineering file: QF-GT-DJD-7.3.2-20 Usability Engineering File	P
	– intended medical indication	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 4, section 1.4	P
	– intended PATIENT population	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 4, section 1.4	P
	– intended part of the body or type of tissue applied to or interacted with	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 4, section 1.4	P
	– intended USER PROFILE	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 4, section 1.5	P
	– intended USE ENVIRONMENT	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 4, section 1.6	P
	– operating principle	QF-GT-DJD-7.3.2-20Usability Engineering File Page 4, section 1.7	P
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	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 6, section 2	P
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.	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 6, section 2	P
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.	Document Reference No. in usability engineering file: QF-GT-DJD-7.3.2-20 Usability Engineering File Page 4, section 1.7	P
	The description of each identified HAZARD-RELATED USE SCENARIO includes all TASKS and their sequences	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 4, section 1.7	P

ANNEX I - IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist			
Clause	Requirement + Test	Result - Remark	Verdict
	The SEVERITY of the possible resulting associated HARM was determined	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 4, section 1.7	P
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:	Document Reference No. in usability engineering file: QF-GT-DJD-7.3.2-20	P
	- all HAZARD-RELATED USE SCENARIOS;		P
	- 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		P
	- 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		N/A
	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	:	N/A
5.6	The MANUFACTURER shall establish and maintain a USER INTERFACE SPECIFICATION	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 7, section 3	P
5.7	The MANUFACTURER shall establish and maintain a USER INTERFACE EVALUATION plan for the USER INTERFACE	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 8, section 4	P
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 .....:	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 7, section 3	P
	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	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 8, section 6	P
	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:	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 9, section 7.2	P
	- provide the materials necessary for training;	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 9, section 7.2	P
	- ensure the materials necessary for training are available;	QF-GT-DJD-7.3.2-12Usability Engineering File Page 9, section 7.2	P

ANNEX I - IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist			
Clause	Requirement + Test	Result - Remark	Verdict
	- make the training available; or	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 9, section 7.2	P
	- make training available to the RESPONSIBLE ORGANIZATION that enables it to train its USERS	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 9, section 7.2	P
5.9	The MANUFACTURER shall perform a SUMMATIVE EVALUATION of each HAZARD-RELATED USE SCENARIO selected in Clause 5.5	Document Reference No. in usability engineering file: QF-GT-DJD-7.3.2-20 Usability Engineering File Page 8,9, section 6	P
	All USE ERRORS and use difficulties that occurred shall be identified	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 8,9, section 6	P
	Where USE ERROR or use difficulty can lead to a HAZARDOUS SITUATION the root causes should be determined	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 8,9, section 6	P
	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;		P
	- if not, then the MANUFACTURER determine whether further improvement of the USER INTERFACE design as it relates to SAFETY is necessary and practicable		N/A
	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:		N/A
	i) Document why improvement is not necessary or not practicable;		N/A
	ii) Identify the data from the USABILITY ENGINEERING PROCESS needed to determine the RESIDUAL RISK related to use; and		N/A
	iii) Evaluate the RESIDUAL RISK according to ISO 14971:2019, Clause 7.3		N/A
5.10	USER INTERFACE OF UNKNOWN PROVENANCE (UOUP) was evaluated according to Annex C rather than the requirements of 5.1 through 5.9.		N/A

Annex C	**Evaluation of a USER INTERFACE OF UNKNOWN PROVENANCE (UOUP)**		P
C.2.1	The MANUFACTURER shall establish a USE SPECIFICATION as required in 5.1.	Document Reference No. in usability engineering file: QF-GT-DJD-7.3.2-20 Usability Engineering File	P

ANNEX I - IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist			
Clause	Requirement + Test	Result - Remark	Verdict
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	Document Reference No. in usability engineering file: QF-GT-DJD-7.3.2-20 Usability Engineering File Page 4, section 1.8	P
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	Document Reference No. in usability engineering file: QF-GT-DJD-7.3.2-20 Usability Engineering File Page 8, section 6	P
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	Document Reference No. in usability engineering file: QF-GT-DJD-7.3.2-20 Usability Engineering File Page 8, section 6	P
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	Document Reference No. in usability engineering file or Risk Management File: GT-RM2017-003	P

ANNEX I - IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist			
Clause	Requirement + Test	Result - Remark	Verdict

Table 5.3	**USABILITY ENGINEERING FILE RESULTS TABLE: RISK ANALYSIS**		**P**
	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	QF-GT-DJD-7.3.2-20 Usability Engineering File	Acceptable according to IEC 62366-1	P
During the identification of HAZARDS and HAZARDOUS SITUATIONS, the following was considered:			—
– USE SPECIFICATION, including USER PROFILE(S) (See 5.1)	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 4, section 1.5	Acceptable according to IEC 62366-1	P
– information on HAZARDS and HAZARDOUS SITUATIONS known for existing USER INTERFACES of MEDICAL DEVICES of a similar type, if available; and	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 4, section 1.5	Acceptable according to IEC 62366-1	P
– identified USE ERRORS (see 5.2).	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 4, section 1.5	Acceptable according to IEC 62366-1	P

Table 5.6	**USABILITY ENGINEERING FILE RESULTS TABLE: USER INTERFACE SPECIFICATION**		**P**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
USER INTERFACE SPECIFICATION	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 7, section 3	Acceptable according to IEC 62366-1	P
The USER INTERFACE SPECIFICATION shall consider:			—
– the USE SPECIFICATION (See 5.1)	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 7, section 3	Acceptable according to IEC 62366-1	P
– the known or foreseeable USE ERRORS associated with the medical device (See 5.2); and	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 7, section 3	Acceptable according to IEC 62366-1	P
– the HAZARD-RELATED USE SCENARIOS (See 5.4)	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 7, section 3	Acceptable according to IEC 62366-1	P

ANNEX I - IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist			
Clause	Requirement + Test	Result - Remark	Verdict

Table 5.6	**USABILITY ENGINEERING FILE RESULTS TABLE: USER INTERFACE SPECIFICATION**		**P**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
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;	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 7, section 3	Acceptable according to IEC 62366-1	P
– an indication as to whether ACCOMPANYING DOCUMENTATION is required; and	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 7, section 3	Acceptable according to IEC 62366-1	P
– an indication as to whether MEDICAL DEVICE specific training is required	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 7, section 3	Acceptable according to IEC 62366-1	P

Table 5.7	**USABILITY ENGINEERING FILE RESULTS TABLE: USER INTERFACE EVALUATION plan**		**P**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
The manufacturer shall establish and maintain a USER INTERFACE EVALUATION plan for the USER INTERFACE	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 8, section 4	Acceptable according to IEC 62366-1	P
The USER INTERFACE EVALUATION plan shall document:			—
a) the objective and identify the method of any planned FORMATIVE EVALUATIONS and SUMMATIVE EVALUATIONS	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 8, section 4	Acceptable according to IEC 62366-1	P
b) if USABILITY TESTS are employed, – document which USER GROUPS are intended to be included in the test;	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 8, section 4	Acceptable according to IEC 62366-1	P
– document the test environment and other conditions of use, based on the USE SPECIFICATION;	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 8, section 4	Acceptable according to IEC 62366-1	P
– specify whether ACCOMPANYING DOCUMENTATION is provided during the test; and	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 8, section 4	Acceptable according to IEC 62366-1	P

ANNEX I - IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist			
Clause	Requirement + Test	Result - Remark	Verdict

Table 5.7	**USABILITY ENGINEERING FILE RESULTS TABLE: USER INTERFACE EVALUATION plan**		**P**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
– 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.	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 8, section 4	Acceptable according to IEC 62366-1	P
The USER INTERFACE evaluation plan for FORMATIVE EVALUATION shall address:			—
a) the evaluation methods being used;	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 8, section 4	Acceptable according to IEC 62366-1	P
b) which part of the USER INTERFACE is being evaluated; and	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 8, section 4	Acceptable according to IEC 62366-1	P
c) when in the USABILITY ENGINEERING PROCESS to perform each of the USER INTERFACE EVALUATIONS.	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 8, section 4	Acceptable according to IEC 62366-1	P
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;	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 8, section 4	Acceptable according to IEC 62366-1	P
b) which part of the USER INTERFACE is being evaluated;	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 8, section 4	Acceptable according to IEC 62366-1	P
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);	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 8, section 4	Acceptable according to IEC 62366-1	P
d) the availability of the ACCOMPANYING DOCUMENTATION and provision of training during the SUMMATIVE EVALUATION; and	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 8, section 4	Acceptable according to IEC 62366-1	P
e) for a USABILITY TEST, – how the characteristics of the test participants are representative of the intended USER PROFILES;	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 8, section 4	Acceptable according to IEC 62366-1	P

ANNEX I - IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist			
Clause	Requirement + Test	Result - Remark	Verdict

Table 5.7	**USABILITY ENGINEERING FILE RESULTS TABLE: USER INTERFACE EVALUATION plan**		**P**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
– justifying how the test participants are grouped into distinct USER GROUPS for the purpose of determining the number of test participants;	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 8, section 4	Acceptable according to IEC 62366-1	P
– the test environment and conditions of use and a rationale for how they are adequately representative of the intended USE ENVIRONMENT;	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 8, section 4	Acceptable according to IEC 62366-1	P
– the definition of CORRECT USE for each HAZARD-RELATED USE SCENARIO; and	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 8, section 4	Acceptable according to IEC 62366-1	P
– the method of collecting data during the USABILITY TEST for the subsequent analysis of observed USE ERRORS and use difficulties.	QF-GT-DJD-7.3.2-20 Usability Engineering File Page 8, section 4	Acceptable according to IEC 62366-1	P