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..... :	**EFSH23090048-IE-01-L02**
Date of issue ..... :	**2024-02-29**
Total number of pages ..... :	**20**
Name of Testing Laboratory preparing the Report ..... :	Eurofins Electrical Testing Service (Shanghai) Co., Ltd Building 18, No. 2168 Chenhang Highway, Minhang District, Shanghai, China
Applicant's name..... :	**GlobTek, Inc.**
Address ..... :	**186 Veterans Dr. 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

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. or G GlobTek,Inc.
Manufacturer ..... :	GlobTek, Inc. 186 Veterans Dr. Northvale, NJ 07647 USA
Model/Type reference ..... :	GTM46360-****, GTM96183-*PD*-USB1C*, GTM96181-*PD*** (Refer to General product information and other remarks)
Ratings ..... :	GTM46360-****: Input:100-240V~, 50-60Hz, Max. 0.75A, Output: 3.0-5.0Vdc, Max. 6.0A, Max. 30W GTM96183-*PD*-USB1C*, GTM96181-*PD***: Input:100-240V~, 50-60Hz, 1.2A, Output: 5.0- 21.0Vdc, Max. 3.0A, Max. 36W

Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):			
☒	**CB Testing Laboratory:**	Eurofins Electrical Testing Service (Shanghai) Co., Ltd	
Testing location/ address.....:		Building 18, No. 2168 Chenhang Highway, Minhang District, Shanghai, China	
Tested by (name, function, signature).....:		Jack Gan Project Manager	
Approved by (name, function, signature)...:		Jackie Zhao Reviewer	
☐	**Testing procedure: CTF Stage 1:**	N/A	
Testing location/ address.....:		N/A	
Tested by (name, function, signature).....:		N/A	
Approved by (name, function, signature)...:		N/A	
☐	**Testing procedure: CTF Stage 2:**	N/A	
Testing location/ address.....:		N/A	
Tested by (name + signature).....:		N/A	
Witnessed by (name, function, signature) .:		N/A	
Approved by (name, function, signature)...:		N/A	
☐	**Testing procedure: CTF Stage 3:**	N/A	
☐	**Testing procedure: CTF Stage 4:**	N/A	
Testing location/ address.....:		N/A	
Tested by (name, function, signature).....:		N/A	
Witnessed by (name, function, signature) .:		N/A	
Approved by (name, function, signature)...:		N/A	
Supervised by (name, function, signature) :		N/A	

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: 6)
Attachment 1 – Canada National Differences: 3 pages

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):
EU Group, Switzerland (CH), Canada (CA), Japan (JP) and United States (US)

☒ **The product fulfils the requirements of EN 60601-1-6: 2010+A1:2015+A2:2021, SN EN 60601-1-6: 2010+A1:2015+A2:2021, CAN/CSA-C22.2 No. 60601-1-6:11 and JIS T 60601-1-6: 2023**
Remarks: No national differences for EU, CH, Japan and United States

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").

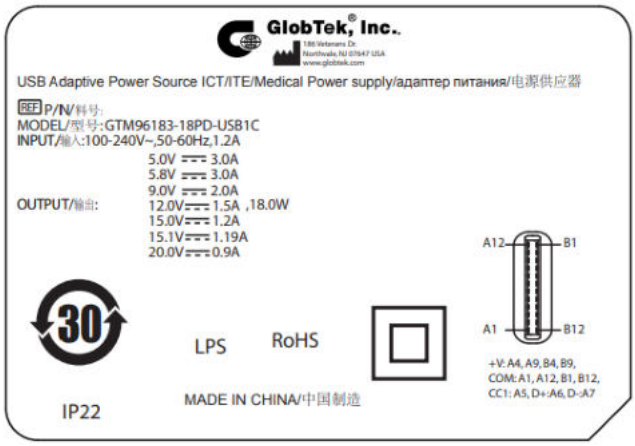
☐ Other: … (to be specified, for example when required by the standard or client, or if national accreditation requirements apply)

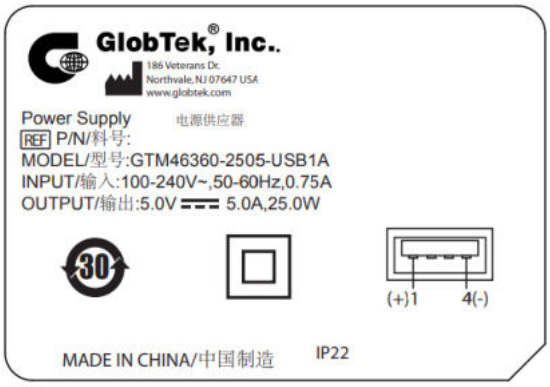
Information on uncertainty of measurement:
The uncertainties of measurement are calculated by the laboratory based on application of criteria given by OD-5014 for test equipment and application of test methods, decision sheets and operational procedures of IECEE.
IEC Guide 115 provides guidance on the 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.

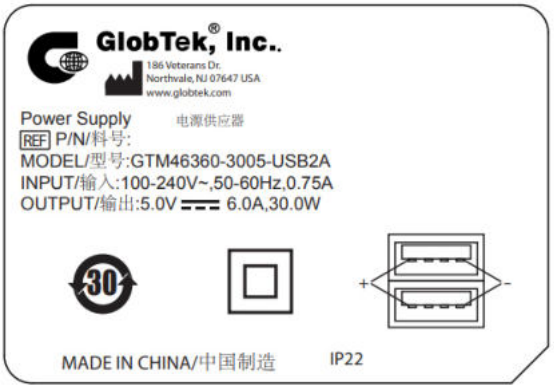
Copy of marking plate:

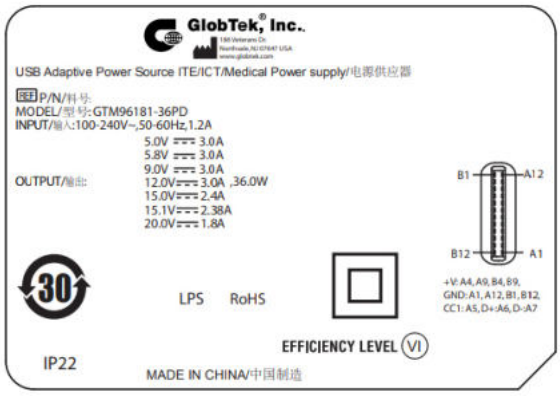
The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

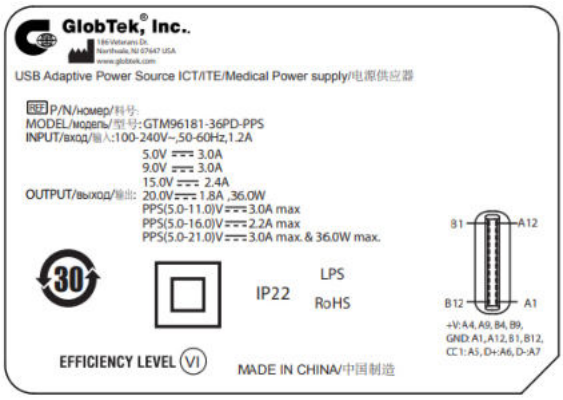
(Typical)

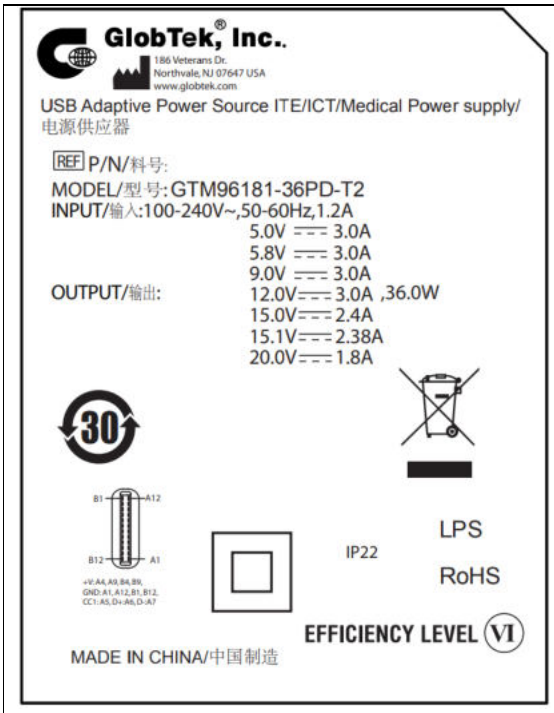


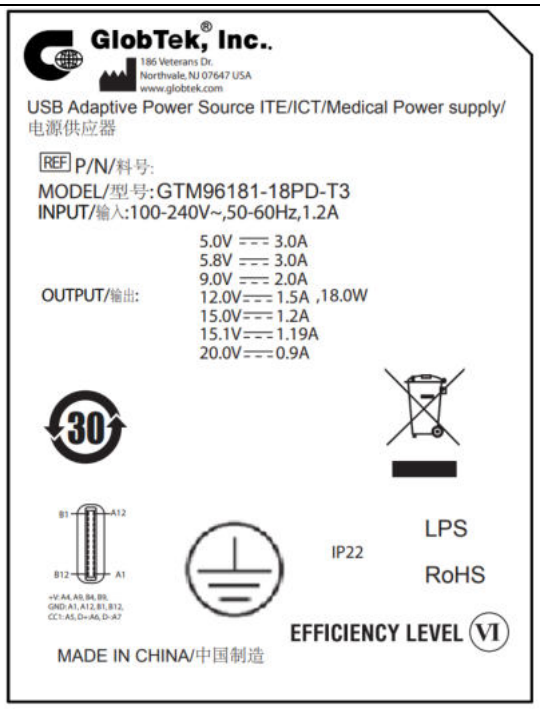












Note:

1, Markings of other models are similar as above except model name and output parameters.

2,  only for Class II models,  only for Class I models

Test item particulars.....:	
Classification of installation and use.....:	portable / Direct plug-in Class I models in home healthcare environment are intended to be permanently installed only.
Supply Connection.....:	Appliance coupler
.....:	
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 .....:	2023-09-06
Date (s) of performance of tests .....:	--

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 only valid in conjunction with IEC 60601-1 test report EFSH23090048-IE-01-L01.

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) ..... :	1. GlobTek, Inc. 186 Veterans Dr. Northvale, NJ 07647 USA 2. GlobTek (Suzhou) Co., Ltd. Building 4, No. 76 JinLing East Road, Suzhou Industrial Park, Suzhou, JiangSu, 215021, China

General product information and other remarks:

Refer to IEC 60601-1 test report EFSH23090048-IE-01-L01.

IEC 60601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
4	**GENERAL REQUIREMENTS**		-
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-7.3.2-9 Usability Engineering File	P
5	**ME EQUIPMENT ACCOMPANYING DOCUMENTS**		--
	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 “ELECTRICAL SPECIFICATIONS” of user manual	P
	The same information is also included in the technical description, if this is provided as a separate document from instructions for use		N/A

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

4	**PRINCIPLES**		--
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-7.3.2-9 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.		P
	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.		P
	Compliance with this subclause to exist when the requirements of this International Standard have been fulfilled.		P
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-7.3.2-9 Usability Engineering File	P
	a) inherently safe design and manufacture;		P
	b) protective measures in the MEDICAL DEVICE itself or in the manufacturing PROCESS; and		P
	c) information for SAFETY and, where appropriate, training to USERS.		P
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-7.3.2-9 Usability Engineering File Page 5, section 1.15	P
4.2	The results of the USABILITY ENGINEERING PROCESS are stored in the USABILITY ENGINEERING FILE .....:	QF-GT-DJD-7.3.2-9 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:		P
	a) the size and COMPLEXITY of the USER INTERFACE		P
	b) the SEVERITY of the HARM associated with the use of the MEDICAL DEVICE		P
	c) the extent or complexity of the USE SPECIFICATION		P
	d) the presence of USER INTERFACE OF UNKNOWN PROVENANCE		N/A

ANNEX I - IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist			
Clause	Requirement + Test	Result - Remark	Verdict
	e) the extent of the modification to an existing MEDICAL DEVICE USER INTERFACE that had been subjected to the USABILITY ENGINEERING PROCESS		N/A
5	**USABILITY ENGINEERING PROCESS**		--
5.1	The MANUFACTURER shall prepare a USE SPECIFCATION. The USE SPECIFICATION shall include the following.....:	Document Reference No. in usability engineering file: Usability Specification：GT-US2021-003 Rev. A.0	P
	– intended medical indication	Specification：GT-US2021-003 Rev. A.0：Cl.1.1.2.1	P
	– intended PATIENT population	Specification：GT-US2021-003 Rev. A.0：Cl.1.1.2.2	P
	– intended part of the body or type of tissue applied to or interacted with	Specification：GT-US2021-003 Rev. A.0：Cl.1.1.2.3	P
	– intended USER PROFILE	Specification：GT-US2021-003 Rev. A.0：Cl.1.1.2.4	P
	– intended USE ENVIRONMENT	Specification：GT-US2021-003 Rev. A.0：Cl.1.1.2.5	P
	– operating principle	QF-GT-DJD-7.3.2-9 Usability Engineering File, section 1.7 and section 2	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	Specification：GT-US2021-003 Rev. A.0：Cl.2.2.	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.	See Appended Table 5.3	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-7.3.2-9 Usability Engineering, section 6, and Specification：GT-US2021-003 Rev. A.0	P
	The description of each identified HAZARD-RELATED USE SCENARIO includes all TASKS and their sequences		P
	The SEVERITY of the possible resulting associated HARM was determined		P

ANNEX I - IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist			
Clause	Requirement + Test	Result - Remark	Verdict
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-7.3.2-9 Usability Engineering File	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	Document Reference No. in USABILITY ENGINEERING FILE:	N/A
5.6	The MANUFACTURER shall establish and maintain a USER INTERFACE SPECIFICATION	See Appended Table 5.6	P
5.7	The MANUFACTURER shall establish and maintain a USER INTERFACE EVALUATION plan for the USER INTERFACE	See Appended Table 5.7	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 .....:	Document References in USABILITY ENGINEERING FILE, including any FORMATVE EVALUATION or required training strategy	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		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:	QF-GT-DJD-7.3.2-9 Usability Engineering File Page 9, section 7.2	P
	- provide the materials necessary for training;		P
	- ensure the materials necessary for training are available;		P
	- make the training available; or		P
	- make training available to the RESPONSIBLE ORGANIZATION that enables it to train its USERS		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-7.3.2-9 Usability Engineering File Page, section 7	P

ANNEX I - IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist			
Clause	Requirement + Test	Result - Remark	Verdict
	All USE ERRORS and use difficulties that occurred shall be identified		P
	Where USE ERROR or use difficulty can lead to a HAZARDOUS SITUATION the root causes should be determined		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;		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		P
	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:		P
	i) Document why improvement is not necessary or not practicable;		P
	ii) Identify the data from the USABILITY ENGINEERING PROCESS needed to determine the RESIDUAL RISK related to use; and		P
	iii) Evaluate the RESIDUAL RISK according to ISO 14971:2019, Clause 7.3		P
5.10	USER INTERFACE OF UNKNOWN PROVENANCE (UOUP) was evaluated according to Annex C rather than the requirements of 5.1 through 5.9.	No UOUP	N/A

Annex C	**Evaluation of a USER INTERFACE OF UNKNOWN PROVENANCE (UOUP)**		--
C.2.1	The MANUFACTURER shall establish a USE SPECIFICATION as required in 5.1.		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

ANNEX I - IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist			
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

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	Specification：GT-US2021-003 Rev. A.0：Cl.2.3.	Performed according to ISO 14971:2019	P
During the identification of HAZARDS and HAZARDOUS SITUATIONS, the following was considered:			—
– USE SPECIFICATION, including USER PROFILE(S) (See 5.1)	Specification：GT-US2021-003 Rev. A.0	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-7.3.2-9 Usability Engineering File Page 4, section 6	Acceptable according to IEC 62366-1	P
– identified USE ERRORS (see 5.2).	QF-GT-DJD-7.3.2-9 Usability Engineering File Page 4, section 6	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	GT-US2021-003 Usability Specification	Acceptable according to IEC 62366-1	P
The USER INTERFACE SPECIFICATION shall consider:			—
– the USE SPECIFICATION (See 5.1)	GT-US2021-003 Usability Specification, section 1.1	Acceptable according to IEC 62366-1	P
– the known or foreseeable USE ERRORS associated with the medical device (See 5.2); and	GT-US2021-003 Usability Specification, section 2.3.3	Acceptable according to IEC 62366-1	P
– the HAZARD-RELATED USE SCENARIOS (See 5.4)	GT-US2021-003 Usability Specification, section 2.3.3	Acceptable according to IEC 62366-1	P
Inputs to the USER INTERFACE SPECIFICATION shall include the following:			—

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**
– 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;		Other method used	N/A
– an indication as to whether ACCOMPANYING DOCUMENTATION is required; and	GT-US2021-003 Usability Specification, section 2.3.8	no issues	P
– an indication as to whether MEDICAL DEVICE specific training is required	GT-US2021-003 Usability Specification, section 2.3.8	no issues	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-7.3.2-9 Usability Engineering File Page 5, section 1.13 and 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-7.3.2-9 Usability Engineering File Page 5, section 1.13, 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-7.3.2-9 Usability Engineering File Page 5, section 1.13, 4 and usability validation file: GT-UV2021-003	Acceptable according to IEC 62366-1	P
– document the test environment and other conditions of use, based on the USE SPECIFICATION;	QF-GT-DJD-7.3.2-9 Usability Engineering File Page 5, section 1.13, 4 and usability validation file: GT-UV2021-003	Acceptable according to IEC 62366-1	P
– specify whether ACCOMPANYING DOCUMENTATION is provided during the test; and	QF-GT-DJD-7.3.2-9 Usability Engineering File Page 5, section 1.13, 4 and usability validation file: GT-UV2021-003	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-7.3.2-9 Usability Engineering File Page 5, section 1.13, 4 and usability validation file: GT-UV2021-003	Acceptable according to IEC 62366-1	P
The USER INTERFACE evaluation plan for FORMATIVE EVALUATION shall address:			—
a) the evaluation methods being used;	GT-UVPLAN2021-003, Usability validation plan, section 5	Acceptable according to IEC 62366-1	P
b) which part of the USER INTERFACE is being evaluated; and	GT-UVPLAN2021-003, Usability validation plan, section 5.1	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-7.3.2-9 Usability Engineering File Page 5, section 1.14	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;	GT-UVPLAN2021-003, Usability validation plan, section 5	Acceptable according to IEC 62366-1	P
b) which part of the USER INTERFACE is being evaluated;	GT-UVPLAN2021-003, Usability validation plan, section 2	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);	GT-UVPLAN2021-003, Usability validation plan, section 6	Acceptable according to IEC 62366-1	P
d) the availability of the ACCOMPANYING DOCUMENTATION and provision of training during the SUMMATIVE EVALUATION; and	GT-UVPLAN2021-003, Usability validation plan, section 1	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;	GT-UVPLAN2021-003, Usability validation plan, section 5.2.1	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;	GT-UVPLAN2021-003, Usability validation plan, section 5.2.1	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;	GT-UVPLAN2021-003, Usability validation plan, section 5.2.1	Acceptable according to IEC 62366-1	P
– the definition of CORRECT USE for each HAZARD-RELATED USE SCENARIO; and	GT-UVPLAN2021-003, Usability validation plan, section 2	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.	GT-UVPLAN2021-003, Usability validation plan, section 5.2.1	Acceptable according to IEC 62366-1	P

ATTACHMENT to TRF IEC60601_1_6L			
Clause	Requirement + Test	Result - Remark	Verdict
ATTACHMENT TO TEST REPORT **IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013, IEC 60601-1-6:2010/AMD2:2020** **CANADA NATIONAL DIFFERENCES** MEDICAL ELECTRICAL EQUIPMENT - PART 1-6: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - COLLATERAL STANDARD: USABILITY			
Differences according to ..... : CAN/CSA-C22.2 No. 60601-1-6:11			
TRF template used:.....: IECEE OD-2020-F3:2022, Ed. 1.2			
Attachment Form No. ..... : CA_ND_IEC60601_1_6L **Attachment Originator.....** : CSA Group **Master Attachment**..... : 2023-06-01			
	National Differences		P
--	The following deviations are intended to meet Canadian product requirements and to align with the Canadian Electrical Code, Part I. IEC 60601-1-6:2010+A1:2013+A2:2020 (edition 3.2) forms the basis for CAN/CSA-C22.2 No. 60601-1-6, which contains the following deviations in addition to those shown in CAN/CSA-C22.2 No. 60601-1:14. [Replace all references to “IEC 60601-1” with “CAN/CSA-C22.2 No. 60601-1”]		P
1.1	[Add the following paragraph] This Standard applies to ME EQUIPMENT and ME SYSTEMS that are intended to be installed or used in accordance with CSA C22.1, Canadian Electrical Code, Part I.		P

ATTACHMENT to TRF IEC60601_1_6L			
Clause	Requirement + Test	Result - Remark	Verdict
2	[Add the following] In this Standard, any reference to International Standards shall be replaced by the relevant National Standard of Canada. Where reference is made to CSA Group publications, such reference shall be considered to refer to the latest edition and all amendments published to that edition. This Standard refers to the following publications, and the years shown indicate the latest editions available at the time of printing: CSA Group C22.1:21 Canadian Electrical Code, Part I C22.2 No. 0:20 General requirements — Canadian Electrical Code, Part II The following National Standards of Canada, published by CSA Group, are adoptions of ISO and IEC Standards. The requirements of these CSA Group Standards shall take precedence over the International Standards on which they are based. Any reference within CAN/CSA-C22.2 No. 60601-1-6 to the International Standard shall be replaced by a reference to the equivalent Canadian Standard. CAN/CSA-C22.2 No. 60601-1:14 (R2018) Medical electrical equipment — Part 1: General requirements for basic safety and essential performance [Replaces IEC 60601-1:2005, IEC Amendment 1:2012, and IEC Amendment 2:2020] CSA IEC 62366-1:15 (R2020) Medical devices — Part 1: Application of usability engineering to medical devices [Replaces IEC 62366-1:2015 and IEC Amendment 1:2020] CSA ISO 14971:21 Medical devices — Application of risk management to medical devices [Replaces ISO 14971:2019]		P

ATTACHMENT to TRF IEC60601_1_6L			
Clause	Requirement + Test	Result - Remark	Verdict
4	[Add the following clause] 4.1A General General requirements applicable to these products are provided in CSA C22.2 No. 0.		P