Test Report issued under the responsibility of:

intertek
Total Quality. Assured.

TEST REPORT
IEC 60601-1
Medical electrical equipment Part 1-6
General requirements for safety - Collateral Standard: Usability

Report Number. ..... :	**200402485SHA-002**
Date of issue ..... :	**2020-06-09**
Total number of pages ..... :	**16**
Name of Testing Laboratory preparing the Report ..... :	Intertek Testing Services Shanghai
Applicant's name ..... :	GlobTek, Inc.
Address ..... :	186 Veterans Dr. Northvale, NJ 07647 USA
Test specification:	
Standard ..... :	IEC 60601-1-6:2010, AMD1:2013 for use in conjunction with IEC 62366:2007, AMD1:2014 and IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1: 2012 or equivalent consolidated version IEC 60601-1:2012 (Edition 3.1)
Test procedure ..... :	CB Scheme
Non-standard test method ..... :	N/A
Test Report Form No. ..... :	IEC60601_1_6H
Test Report Form(s) Originator .... :	TÜV Rheinland of North America
Master TRF ..... :	Dated 2017-08

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 CB 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 CB Testing Laboratory. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.

Test item description ..... :	Medical Power Supply
Trade Mark ..... :	GlobTek, Inc.
Manufacturer ..... :	Same as applicant
Model/Type reference ..... :	GT*86101-***-W2*** (Refer to general product information for details.)
Ratings ..... :	Input：100-240V~, 50-60Hz or 50/60Hz, 0.3A; Output: 5.95-24Vdc, Max.2.0A, Max.12W

Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):			
☒	**CB Testing Laboratory:**	Intertek Testing Services Shanghai	
Testing location/ address.....:		Building No.86, 1198 Qinzhou Road (North), 200233 Shanghai, China	
Tested by (name, function, signature).....:		Yann Yan (Engineer)	yann yan
Approved by (name, function, signature)...:		Larry Zhong (Mandated Reviewer)	Larry Zhong
☐	**Testing procedure: CTF Stage 1:**		
Testing location/ address.....:			
Tested by (name, function, signature).....:			
Approved by (name, function, signature)...:			
☐	**Testing procedure: CTF Stage 2:**		
Testing location/ address.....:			
Tested by (name + signature) .....:			
Witnessed by (name, function, signature) .:			
Approved by (name, function, signature)...:			
☐	**Testing procedure: CTF Stage 3:**		
☐	**Testing procedure: CTF Stage 4:**		
Testing location/ address.....:			
Tested by (name, function, signature).....:			
Witnessed by (name, function, signature) .:			
Approved by (name, function, signature)...:			
Supervised by (name, function, signature) :			

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

ANNEX I – IEC 62366:2007 + A1:2014 – Usability engineering process checklist (Pages: 9)

Summary of testing:

Tests performed (name of test and test clause):	**Testing location:**
None	N/A

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

The requirements of USA and Canada have been checked and found to include no national differences from the IEC 60601-1-6:2010, AMD1:2013.

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

Copy of marking plate:

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

See IEC 60601-1 Test Report No. 200402485SHA-001.

Test item particulars.....:	
Classification of installation and use.....:	Direct plug-in for power adapter model.
Supply Connection.....:	Direct plug-in for power adapter model.
.....:	
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 .....:	No test required.
Date (s) of performance of tests.....:	No test required.

General remarks:

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

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

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

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

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

Name and address of factory (ies).....:	See IEC 60601-1 Test Report No. 200402485SHA-001.

General product information:

See IEC 60601-1 Test Report No. 200402485SHA-001.

IEC 60601-1-6:2010 +A1:2013			
Clause	Requirement + Test	Result - Remark	Verdict
4.0	**GENERAL REQUIREMENTS**		P
4.2	USABILITY ENGINEERING PROCESS complies with IEC 62366 including amended definitions. Excludes production and post-production monitoring, and maintenance of the USABILITY ENGINEERING PROCESS	See attached IEC 62366 ANNEX I	P
	Inspection of the USABILITY ENGINEERING FILE verified that the MANUFACTURER		P
	– established a USABILITY ENGINEERING PROCESS	See QF-GT-DJD-7.3.2-6 Usability Engineering File P2/1.2	P
	– established acceptance criteria for USABILITY; and	See QF-GT-DJD-7.3.2-6 Usability Engineering File P5/1.15	P
	– demonstrated that the acceptance criteria for USABILITY have been met.	See QF-GT-DJD-7.3.2-6 Usability Engineering File P5/1.15	P
5	**REPLACEMENT OF REQUIREMENTS GIVEN IN IEC 62366**		**P**
	The instructions for use include a brief description of the ME EQUIPMENT, its physical operating principles and significant physical and performance characteristics relevant to its USABILITY	Refer to “POWER SUPPLY INFORMATION” and “ELECTRICAL SPECIFICATIONS” 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		P

ANNEX I - IEC 62366:2007 + A1:2014 – Usability engineering process checklist			
Clause	Requirement + Test	Result - Remark	Verdict

4	**PRINCIPLES**		**P**
4.1.1	The MANUFACTURER has established, documented and maintains a USABILITY ENGINEERING PROCESS addressing USER interactions with the MEDICAL DEVICE according to the ACCOMPANYING DOCUMENT	QF-GT-DJD-7.3.2-6Usability Engineering File	P
4.1.2	The USABILITY ENGINEERING PROCESS complies with this standard and the acceptance criteria in the USABILITY VALIDATION plan have been met	QF-GT-DJD-7.3.2-6Usability Engineering File	P
4.1.3	Information for SAFETY used as a RISK CONTROL measure has been evaluated according to the USABILITY ENGINEERING PROCESS	QF-GT-DJD-7.3.2-6Usability Engineering File Page 5 section1.15	P
4.2	The results of the USABILITY ENGINEERING PROCESS are recorded in the USABILITY ENGINEERING FILE..... :	QF-GT-DJD-7.3.2-6Usability Engineering File	P
4.3	The USABILITY ENGINEERING PROCESS is scaled-up or scaled-down based on the significance of the modification as determined by the results of the RISK ANALYSIS ..... :	QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 6	P

5	**USABILITY ENGINEERING PROCESS**		**P**
5.1	The application of the MEDICAL DEVICE is specified in the USABILITY ENGINEERING FILE ..... :	Document Reference No. in USABILITY ENGINEERING FILE: QF-GT-DJD-7.3.2-6Usability Engineering File	P
	– intended medical indication	QF-GT-DJD-7.3.2-6Usability Engineering File Page 4, section 1.4	P
	– intended PATIENT population	QF-GT-DJD-7.3.2-6Usability 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-7.3.2-6Usability Engineering File Page 4, section 1.4	P
	– intended USER PROFILE	QF-GT-DJD-7.3.2-6Usability Engineering File Page 4, section 1.5	P
	– intended conditions of use	QF-GT-DJD-7.3.2-6Usability Engineering File Page 4, section 1.6	P
	– operating principle	QF-GT-DJD-7.3.2-6Usability Engineering File Page 4, section 1.7	P

ANNEX I - IEC 62366:2007 + A1:2014 – Usability engineering process checklist			
Clause	Requirement + Test	Result - Remark	Verdict
5.2	The frequently used functions that involve USER interaction with the MEDICAL DEVICE are recorded in the USABILITY ENGINEERING FILE ..... :	Document Reference No. in USABILITY ENGINEERING FILE: QF-GT-DJD-7.3.2-6Usability Engineering File Page 6, section 2	P
5.3.1	The MANUFACTURER identified characteristics related to SAFETY that focus on USABILITY	See Table 5.3.1 QF-GT-DJD-7.3.2-6Usability Engineering File Page 6, section 2	P
5.3.2	The MANUFACTURER identified known or foreseeable HAZARDS related to USABILITY	See Table 5.3.2 QF-GT-DJD-7.3.2-6Usability Engineering File Page 6, section 2	P
	Reasonably foreseeable sequences or combinations of events involving the USER INTERFACE that can result in a HAZARDOUS SITUATION associated with the MEDICAL DEVICE are identified	QF-GT-DJD-7.3.2-6Usability Engineering File Page 6, section 2	P
	The SEVERITY of the resulting possible HARM was determined	QF-GT-DJD-7.3.2-6Usability Engineering File Page 6, section 2	P
5.4	The MANUFACTURER determined the PRIMARY OPERATING FUNCTIONS and recorded them in the USABILITY FILE	Document Reference No. in USABILITY ENGINEERING FILE: QF-GT-DJD-7.3.2-6Usability Engineering File Page 4, section 1.7	P
	The inputs to the PRIMARY OPERATING FUNCTIONS included frequently used functions and functions related to SAFETY of the MEDICAL DEVICE	QF-GT-DJD-7.3.2-6Usability Engineering File Page 4, section 1.7	P
5.5	The MANUFACTURER developed the USABILITY SPECIFICATION	See Table 5.5 QF-GT-DJD-7.3.2-6Usability Engineering File Page 6, section 1.18	P
5.6	The MANUFACTURER prepared a USABILITY VALIDATION plan	See Table 5.6 QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 4	P
5.7	The MANUFACTURER designed and implemented the USER INTERFACE as described in the USABILITY SPECIFICATION ..... :	See 5.8 and 5.9 QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 3	—
5.8	The MANUFACTURER verified the implementation of the MEDICAL DEVICE USER INTERFACE design against the requirements of the USABILITY SPECIFICATION	Document Reference No. in USABILITY ENGINEERING FILE: QF-GT-DJD-7.3.2-6Usability Engineering File Page 6, section 1.16	P

ANNEX I - IEC 62366:2007 + A1:2014 – Usability engineering process checklist			
Clause	Requirement + Test	Result - Remark	Verdict
5.9	The MANUFACTURER VALIDATED USABILITY of the MEDICAL DEVICE according to the USABILITY VALIDATION plan	Document Reference No. in USABILITY ENGINEERING FILE: QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 4	P
	If the acceptance criteria are not met and no further improvements are practicable, the medical benefits outweigh the risk	Document Reference No. in USABILITY ENGINEERING FILE: USABILITY ENGINEERING FILE: QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 4	P
5.10	USER INTERFACE OF UNKNOWN PROVENANCE (UOUP) was evaluated according to Annex K rather than the requirements of 5.1 through 5.9.	See Annex K below	P
6	**ACCOMPANYING DOCUMENT**		**P**
	If provided, the ACCOMPANYING DOCUMENT includes a summary of the application specification		P
	If provided, the ACCOMPANYING DOCUMENT includes a concise description of the ME EQUIPMENT, its operating principles and significant physical and performance characteristics, and intended USER PROFILE	Reference to instructions for use SPEC /page 10-11 QF-GT-DJD-7.3.2-6Usability Engineering File Page 4, section 1.7	P
	If provided, the ACCOMPANYING DOCUMENT is written at a level consistent with the USER PROFILE.	English	P
	If the ACCOMPANYING DOCUMENT is provided electronically, the USABILITY ENGINEERING PROCESS included consideration of which information also needs to be provided as hard copy or as markings on the MEDICAL DEVICE		P
7	**TRAINING AND MATERIALS FOR TRAINING**		**P**
	When training is required for the safe and effective use of PRIMARY OPERATING FUNCTIONS, the ACCOMPANYING DOCUMENT describes the available training options	QF-GT-DJD-7.3.2-6Usability Engineering File Page 9, section 7.2	P
	When training is required, the INTENDED USE and USER PROFILE(S) are the basis for training and training material	QF-GT-DJD-7.3.2-6Usability Engineering File Page 9, section 7.2	P
Annex K	**Evaluation of a USER INTERFACE OF UNKNOWN PROVENANCE (UOUP)**		**P**

ANNEX I - IEC 62366:2007 + A1:2014 – Usability engineering process checklist			
Clause	Requirement + Test	Result - Remark	Verdict
K.2.1	The MANUFACTURER established an application specification as required in 5.1.	Document Reference No. in USABILITY ENGINEERING FILE: QF-GT-DJD-7.3.2-6Usability Engineering File	P
K.2.2	The MANUFACTURER identified the PRIMARY OPERATING FUNCTIONS of the MEDICAL DEVICE with UOUP as required by 5.4.	Document Reference No. in USABILITY ENGINEERING FILE: QF-GT-DJD-7.3.2-6Usability Engineering File Page 4, section 1.7	P
K.2.3	Relevant instances of USE ERROR are recorded in the USABILITY ENGINEERING FILE and addressed in K.2.4 and K.2.5.	Document Reference No. in USABILITY ENGINEERING FILE: QF-GT-DJD-7.3.2-6Usability Engineering File Page 4, section 1.8	P
K.2.4	The MANUFACTURER reviewed the RISK ANALYSIS of the MEDICAL DEVICE with UOUP. The HAZARDS and HAZARDOUS SITUATIONS associated with USABILITY or with PRIMARY OPERATING FUNCTIONS were identified.	Document Reference No. in USABILITY ENGINEERING FILE: QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 6	P
K.2.5	The MANUFACTURER verified that adequate RISK CONTROL measures were implemented for all identified HAZARDS and HAZARDOUS SITUATIONS identified in K.2.4.	Document Reference No. in USABILITY ENGINEERING FILE: QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 6	P
	Changes to the USER INTERFACE were made to reduce RISK to an acceptable level, and those changes meet the requirements of 5.1 through 5.9.	QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 6	P
K.2.6	The MANUFACTURER re-evaluated the overall RESIDUAL RISK according to ISO 14971:2007, 6.4.	Document Reference No. in USABILITY ENGINEERING FILE or RISK MANAGEMENT FILE: GT-RM2015-001	P
K.2.7	The ACCOMPANYING DOCUMENT of the UOUP contains an adequate summary of the application specification.	QF-GT-DJD-7.3.2-6Usability Engineering File	P

ANNEX I - IEC 62366:2007 + A1:2014 – Usability engineering process checklist			
Clause	Requirement + Test	Result - Remark	Verdict

Table 5.3.1	**USABILITY ENGINEERING FILE RESULTS TABLE: Characteristics related to SAFETY**		**P**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
An identification of characteristics related to SAFETY that focused on USABILITY was performed according to ISO 14971:2007, Clause 4.2	QF-GT-DJD-7.3.2-6Usability Engineering File		P
During the identification of characteristics related to SAFETY, the following was considered:			—
– application specification, including USER PROFILE(S)	QF-GT-DJD-7.3.2-6Usability Engineering File Page 4, section 1.5		P
– frequently used functions	QF-GT-DJD-7.3.2-6Usability Engineering File Page 4, section 1.6		P

Table 5.3.2	**USABILITY ENGINEERING FILE RESULTS TABLE: Identification of known or foreseeable HAZARDS and HAZARDOUS SITUATIONS**		**P**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
Identification of known or foreseeable HAZARDS related to USABILITY according to ISO 14971:2007, Cl. 4.3	QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 5 Annex A		P
The identification of HAZARDS considers HAZARDS to PATIENTS, USERS and other persons	QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 5 Annex A		P
Reasonably foreseeable sequences or combinations of events involving the user interface that can result in a HAZARDOUS SITUATION associated with the MEDICAL DEVICE are identified	QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 5 Annex A		P
The SEVERITY of the resulting possible HARM was determined	QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 5 Annex A		P
During the identification of HAZARDS and HAZARDOUS SITUATIONS, the following was considered:			—

ANNEX I - IEC 62366:2007 + A1:2014 – Usability engineering process checklist			
Clause	Requirement + Test	Result - Remark	Verdict

Table 5.3.2	**USABILITY ENGINEERING FILE RESULTS TABLE: Identification of known or foreseeable HAZARDS and HAZARDOUS SITUATIONS**		**P**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
– application specification, including USER PROFILE(S)	QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 5 Annex A		P
– task related requirements	QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 5 Annex A		P
– context of use	QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 5 Annex A		P
– information on HAZARDS and HAZARDOUS SITUATIONS known for existing USER INTERFACES of MEDICAL DEVICES of a similar type, if available	QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 5 Annex A		P
– preliminary USE SCENARIOS	QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 5 Annex A		P
– possible USE ERRORS	QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 5 Annex A		P
– if an incorrect mental model of the operation of the MEDICAL DEVICE can cause a USE ERROR resulting in a HAZARDOUS SITUATION	QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 5 Annex A		P
– results of the review of the USER INTERFACE	QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 5 Annex A		P

ANNEX I - IEC 62366:2007 + A1:2014 – Usability engineering process checklist			
Clause	Requirement + Test	Result - Remark	Verdict

Table 5.5	**USABILITY ENGINEERING FILE RESULTS TABLE: USABILITY SPECIFICATION**		**P**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
USABILITY SPECIFICATION	QF-GT-DJD-7.3.2-6Usability Engineering File		P
The USABILITY SPECIFICATION provides:			—
– testable requirements for USABILITY VERIFICATION	QF-GT-DJD-7.3.2-6Usability Engineering File Page 7, section 3		P
– testable requirements for USABILITY of PRIMARY OPERATING FUNCTIONS including criteria for determining the adequacy of RISK CONTROL achieved by the USABILITY ENGINEERING PROCESS.	QF-GT-DJD-7.3.2-6Usability Engineering File Page 7, section 3		P
Inputs to the USABILITY SPECIFICATION include the following:			—
– application specification	QF-GT-DJD-7.3.2-6Usability Engineering File Page 6, section 2		P
– PRIMARY OPERATING FUNCTIONS	QF-GT-DJD-7.3.2-6Usability Engineering File Page 4, section 1.7		P
– HAZARDS and HAZARDOUS SITUATIONS related to USABILITY	QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 6		P
– known or foreseeable USE ERRORS associated with the MEDICAL DEVICE	QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 5 Annex A		P
The USABILITY SPECIFICATION describes:			—
– USE SCENARIOS related to the PRIMARY OPERATING FUNCTIONS	QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 6		P
– frequent USE SCENARIOS	QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 6		P

ANNEX I - IEC 62366:2007 + A1:2014 – Usability engineering process checklist			
Clause	Requirement + Test	Result - Remark	Verdict

Table 5.5	**USABILITY ENGINEERING FILE RESULTS TABLE: USABILITY SPECIFICATION**		**P**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
– reasonably foreseeable worst case USE SCENARIOS	QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 5 Annex A		P
– USER INTERFACE requirements for the PRIMARY OPERATING FUNCTIONS, including those to mitigate RISK	QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 5 Annex A		P
– requirements for determining whether PRIMARY OPERATING FUNCTIONS are easily recognizable by the USER.	QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 5 Annex A		P

Table 5.6	**USABILITY ENGINEERING FILE RESULTS TABLE: USABILITY VALIDATION plan**		**P**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
USABILITY VALIDATION plan	QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 4		P
The USABILITY VALIDATION plan specifies:			—
– any method used for VALIDATION of the USABILITY of PRIMARY OPERATING FUNCTIONS	QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 4		P
– the criteria for determining successful VALIDATION of the USABILITY of the PRIMARY OPERATING FUNCTIONS based on the USABILITY SPECIFICATION	QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 4		P
– the involvement of representative intended USERS	QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 4		P
The USABILITY VALIDATION plan addresses:			—
– frequent USE SCENARIOS	QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 4		P

ANNEX I - IEC 62366:2007 + A1:2014 – Usability engineering process checklist			
Clause	Requirement + Test	Result - Remark	Verdict

Table 5.6	**USABILITY ENGINEERING FILE RESULTS TABLE: USABILITY VALIDATION plan**		**P**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
– reasonably foreseeable worst case USE SCENARIOS identified in the USABILITY SPECIFICATION	QF-GT-DJD-7.3.2-6Usability Engineering File Page 8, section 4		P