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TEST REPORT
IEC 60601-1-11
MEDICAL ELECTRICAL EQUIPMENT –

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.	161200816SHA-002
Date of issue	2017-04-17
	Modification 1: 2019-08-19
Total number of pages	**5**
Name of Testing Laboratory preparing the Report	Intertek Testing Services Shanghai Building No. 86, 1198 Qinzhou Road (North), 200233 Shanghai, China
Applicant's name	GlobTek, Inc.
Address	186 Veterans Dr. Northvale, NJ 07647 USA
Test specification:	
Standard	IEC 60601-1-11:2015 (Second Edition) for use in conjunction with IEC 60601-1:2012 (Third Edition) + A1:2012
Test procedure	CB Scheme
Non-standard test method	N/A
Test Report Form No.	IEC60601_1_11C
Test Report Form(s) Originator.	UL(US)
Master TRF	2015-03

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*961200P**** and GT*96900P****and GT*41133-***** (Refer to general product information for details.
Ratings ..... :	For GT*961200P**** and GT*96900P****: Input:100-240V~,50-60Hz, 1.5A; For GT*41133-*****: Input:100-240V~, 50-60Hz or 50-400Hz, 1.5A; For all models: Output: Refer to general product information for details.

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	
☐	**Associated CB Testing Laboratory:**		
Testing location/ address.....:			
Tested by (name, function, signature).....:		James Fu (Project engineer)	James Fu
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):

None

Summary of testing:

Tests performed (name of test and test clause):	**Testing location:**
Modification 1:2019-08-19 **No testing requirement**	N/A

Summary of compliance with National Differences:

List of countries addressed

See the original report 161200816SHA-002

☒ The product fulfils the requirements of IEC 60601-1-11: 2015 (Second Edition)

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 161200816SHA-001 and 161200816SHA-001-M1.

Test item particulars.....:	See IEC 60601-1 Test Report 161200816SHA-001 and 161200816SHA-001-M1.
Classification of installation and use.....	Portable for power adapter model. Final determination in end product evaluation for open frame model.
Intended use (Including type of patient, application location) ..... :	Lay operator / Home healthcare environment PSU (external power adapter or internal power supply board)
Mode of operation ..... :	Continuous
Supply Connection.....:	Appliance coupler for power adapter model. Final determination in end product evaluation for open frame model.
Accessories and detachable parts included .....:	None
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 testing requirement**
Date (s) of performance of tests .....:	**No testing requirement**

- Normal condition.....: N.C.	- Single fault condition .....: S.F.C.
- Means of Operator protection .....: MOOP	- Means of Patient protection .....: MOPP

General remarks:

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

This report shall not be reproduced except in full without the written approval of the testing laboratory. List of test equipment must be kept on file and available for review. Additional test data and/or information provided in the attachments to this report.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.
This Test Report Form is intended for the evaluation of medical electrical equipment and medical electrical systems used in the home healthcare environment in accordance with IEC 60601-1-11.
This Test Report Form can be used to complement the IEC 60601-1 Test Report.

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

General product information:

See IEC 60601-1 Test Report 161200816SHA-001 and 161200816SHA-001-M1

Modification 1:

The original test report ref. No. 161200816SHA-002 dated 2017-03-17, was modified on 2019-8-19 to include the following changes and/or additions:

1. **Updated the Model Similarity in the general product information, refer to report 161200816SHA-001-M1 for details.**

   Concerning above change, no testing is required.

This modification report should be used in conjunction with the original report No. 161200816SHA-002