TEST REPORT
IEC 60601-1
Medical Electrical Equipment
Part 1: General requirements for basic safety and essential performance

Report Number.	REP048180
Date of issue	2024-06-28
Total number of pages	13, see page 4 for attachment
Name of Testing Laboratory preparing the Report	Nemko Shanghai Ltd. Shenzhen Branch
Applicant's name	GlobTek, Inc.
Address	186 Veterans Drive Northvale NJ 07647 United States of America
Test specification:	
Standard	IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
Test procedure	Compliance Testing
Non-standard test method	N/A
TRF template used	IECEE OD-2020-F1:2020, Ed.1.3
Test Report Form No.	IEC60601_1U
Test Report Form(s) Originator	UL(US)
Master TRF	2023-08-24

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Test item description..... :	ICT/ITE Power Supply
Trade Mark(s) ..... :	GlobTek, Inc.
Manufacturer ..... :	Same as applicant
Model/Type reference..... :	GT*41061-*** The 1st '*' part can be 'M' or '-' or 'H' for market identification and not related to safety. The 2nd '*' part denotes the rated output wattage designation, which can be "01" to "18", with interval of 1. The 3rd '*' part denotes the standard rated output voltage designation, which can be "12", "18", "24" or "30". The 4th '*' part is optional, which can be "-0.1" to "-7.0" with interval of 0.1 to denote voltage deviation or blank to indicate no voltage different. The result by subtracting the deviation value from the standard rated output voltage denotes the rated output voltage, with a range of 5 - 30 volts. The standard rated output voltage is separately 12V, 18V, 24V and 30V.
Ratings..... :	Input: 0.6A 100-240V~ 50-60Hz Output: 5-30Vdc, Max. 3.6A, Max. 18W See General product information for details.

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

☒	**Testing Laboratory:**	Nemko Shanghai Ltd. Shenzhen Branch	
Testing location/ address ..... :		2nd floor of Building 1, Yizhongli Science and Technology Park, No.36 Gaoxin North Third Road, Songpingshan Community, Xili Street, Nanshan District, Shenzhen, Guangdong,China	
Tested by (name, function, signature)..... :		Wesley Yao (Project Handler)	Wesley Yao
Approved by (name, function, signature) .. :		Bingo Yang (Verificator)	Bingo Yang
☐	**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, function, 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):

Attachment 1 – Photos (1 page)

Summary of testing:

Tests performed (name of test and test clause):	**Testing location:**
5.7: Humidity and preconditioning treatment 8.7: Leakage current 8.8.3: Dielectric strength Note: The decision rule of conformity of this test report is following the requirements of the requested standard in this test report, and agreed among testing laboratory and manufacture(applicant) to exclude the consideration of Measurement Uncertainty.	See Page 2

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

N/A

☐ The product fulfils the requirements of

Statement concerning the uncertainty of the measurement systems used for the tests

(may be required by the product standard or client)

☐ **Internal procedure used for type testing through which traceability of the measuring uncertainty has been established:**

Procedure number, issue date and title:

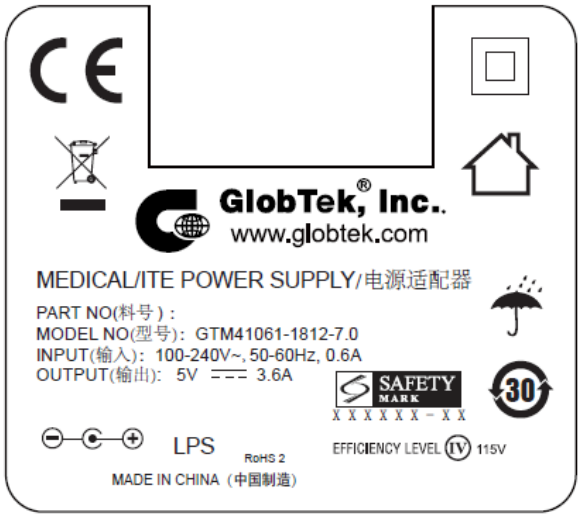
Calculations leading to the reported values are on file with the NCB and testing laboratory that conducted the testing.

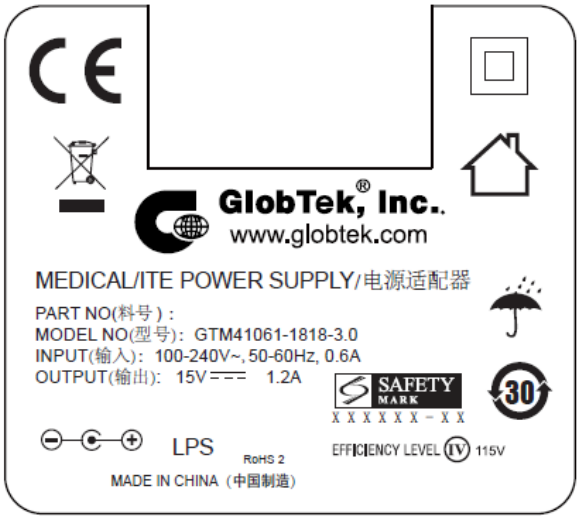
☒ **Statement not required by the standard used for type testing**

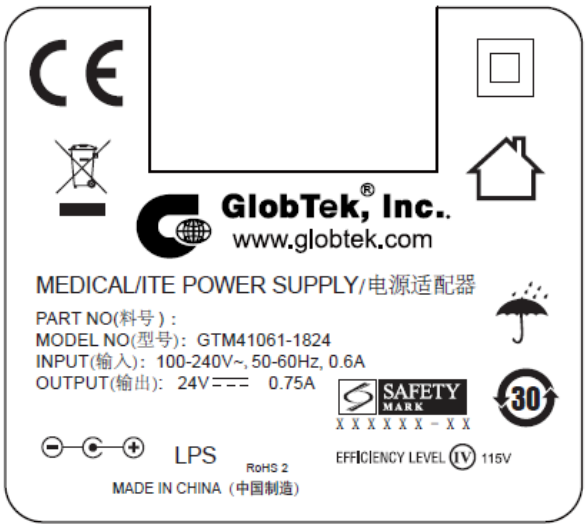
(Note: When IEC or ISO standard requires a statement concerning the uncertainty of the measurement systems used for tests, this should be reported above. The informative text in parenthesis should be delete in both cases after selecting the applicable option)

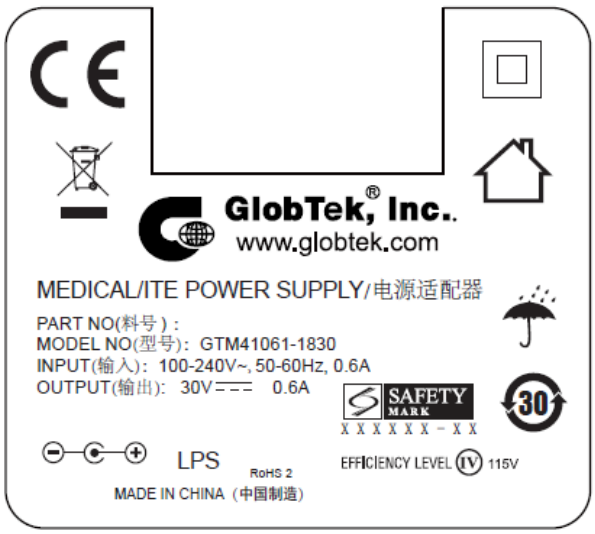
Copy of marking plate :

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.









Notes:
All models labels are in the same design except for type designation and output rating. Above labels are representing the other models.

Test item particulars..... :	
Classification of installation and use..... :	Class II, AC Adapter
Supply Connection ..... :	AC Plug
Device type (component/sub-assembly/ equipment/ system)……..:	Component, AC Adapter
Intended use (Including type of patient, application location)……:	AC Adapter, no applied part
Mode of operation……:	Continuous
Accessories and detachable parts included……...:	None
Other options include……...:	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 was not evaluated for the requirement……...:	N/E (collateral standards only)
- test object does not meet the requirement.....:	F (Fail)
Abbreviations used in the report	
- normal condition……: N.C.	- single fault condition..... : S.F.C.
- means of Operator protection ……: MOOP	- means of Patient protection ... : MOPP
Testing.....:	
Date of receipt of test item .....:	2024-06-20
Date (s) of performance of tests.....:	2024-06-20 – 2024-06-27
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.**	
When differences exist; they shall be identified in the General product information section.	
Name and address of factory (ies) .....:	1. GlobTek, Inc. 186 Veterans Drive Northvale NJ 07647 United States of America 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:

The equipment under tests is Class II AC Adapter intended for use with medical electrical equipment. It provides 2MOPP between input to output and input to enclosure.

The AC Adapter is provided with plastic enclosure without openings. The enclosure is designed as two parts covering the top and bottom halves of the equipment.

The equipment has two structures, Structure A is coated glue on the PCB and components, and Structure B is not coated glue.

Models difference:
All models are same except model name, output rating, turns of primary and secondary winding of transformer (T1) and some non-critical components rating. Detail see below Table 1.

Table 1

Model	Rated output voltage range	Max. rated output current	Max. rated output power	Secondary hatsink	Typical model
GT*41061-*12*	5-12Vdc	3.6A	18W	Have	GTM41061-1812-7.0
GT*41061-*18*	12.1-18Vdc	1.49A	18W	Have	GTM41061-1818-3.0
GT*41061-*24*	18.1-24Vdc	1.0A	18W	Have	GTM41061-1824
GT*41061-*30*	24.1-30Vdc	0.75A	18W	No	GTM41061-1830

If not specified, All tests were performed under the model name GTM41061-1830 (30Vdc, 0.6A) and GTM41061-1812-7.0 (5Vdc, 3.6A) with structure B, which represents the worst condition.

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Clause	Requirement + Test	Result - Remark	Verdict

5	**GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT**		**P**
5.7	ME EQUIPMENT or parts thereof affected by climatic conditions were set up completely, or partially, with covers detached and subjected to a humidity preconditioning prior to tests of Clauses 8.7.4 and 8.8.3……..:	Climatic preconditioning Performed.	**P**
	ME EQUIPMENT heated to a temperature between T and T + 4°C for at least 4 h and placed in a humidity chamber and ambient within 2 °C of T in range of +20°C to +30°C for indicated time	Humidity: 95 %. Temperature: 30 °C. Time: 168 h	**—**
8	**PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT**		**P**
8.7	**LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS**		**P**
8.7.1	a) Electrical isolation providing protection against electric shock limits currents to values in 8.7.3……..:	See appended table 8.7.	**P**
	b) Specified values of EARTH LEAKAGE, TOUCH, PATIENT LEAKAGE, and PATIENT AUXILIARY CURRENTS applied in combination of conditions in appended Table 8.7……..:	See appended table 8.7.	**P**
8.7.2	Allowable values specified in 8.7.3 applied under SINGLE FAULT CONDITIONS of 8.1 b), except		**N/A**
	– where insulation used in conjunction with a PROTECTIVE EARTH CONNECTION, insulation short circuited only under conditions in 8.6.4 b)	Not used.	**N/A**
	– the only SINGLE FAULT CONDITION for EARTH LEAKAGE CURRENT was interruption of one supply conductor at a time		**N/A**
	– LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT not measured in SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION		**N/A**
	SINGLE FAULT CONDITIONS not applied at same time as special test conditions of MAXIMUM MAINS VOLTAGE on APPLIED PARTS and non-PROTECTIVELY EARTHED parts of ENCLOSURE		**N/A**
8.7.3	**Allowable Values**		**P**
	a) Allowable values in 8.7.3 b), c), and d) measured based on, and are relative to currents in Fig 12 a), or by a device measuring frequency contents of currents as in Fig 12 b……..:	See appended table 8.7	**P**
	b) Allowable values of PATIENT LEAKAGE and AUXILIARY CURRENTS are according to Tables 3 & 4, and values of a.c. are relative to currents having a frequency not less than 0.1Hz……..:		**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	c) TOUCH CURRENT did not exceed 100µA in NORMAL CONDITION and 500µA in SINGLE FAULT CONDITION (I_{TNC}, I_{TSFC})……..:	See appended table 8.7	**P**
	d) EARTH LEAKAGE CURRENT did not exceed 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION (I_{ENC}, I_{ESFC})……..:		**N/A**
	Higher values of EARTH LEAKAGE CURRENT permitted for PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit supplying only this ME EQUIPMENT according to local regulations or IEC 60364-7-710……:		**N/A**
	e) LEAKAGE CURRENTS, regardless of waveform and frequency, did not exceed 10 mA r.m.s. in NORMAL or in SINGLE FAULT CONDITION (measured with a non-frequency-weighted device……..:	See appended table 8.7	**P**
	f) LEAKAGE CURRENTS flowing in a FUNCTIONAL EARTH CONDUCTOR in a non-PERMANENTLY INSTALLED ME EQUIPMENT are 5 mA in NORMAL CONDITION, 10 mA in SINGLE FAULT CONDITION….:		**N/A**
8.7.4	LEAKAGE and PATIENT AUXILIARY CURRENTS measurements……..:	See appended table 8.7	**P**
8.8.3	**Dielectric Strength**		**P**
	Solid insulating materials with a safety function withstood dielectric strength test voltages ……..:	See appended Table 8.8.3	**P**

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Clause	Requirement + Test	Result - Remark	Verdict

8.7	**TABLE: leakage current**	**P**

Type of leakage current and test condition (including single faults)	**Supply voltage (V)**	**Supply frequency (Hz)**	**Measured max. value (µA)**		**Remarks**
Fig. 13 - Earth Leakage (ER)	—	—	Before humidity	After humidity	Maximum allowed values: 5 mA NC; 10 mA SFC
Fig. 13 - Earth Leakage (ER)	—	—	Before humidity	After humidity	Measured with non-frequency-weighted device Maximum allowed values: 10 mA NC and SFC
Fig. 14 - Touch Current (TC)	—	—	Before humidity	After humidity	Maximum allowed values: 100 µA NC; 500 µA SFC
MD was connected between GND and output connector					
NC, S1=1, S5=0	264	60	27.0	31.2	Limit: 100uA
NC, S1=1, S5=1	264	60	28.7	32.2	Limit: 100uA
SFC, S1=0, S5=0	264	60	57.6	62.8	Limit: 500uA
SFC, S1=0, S5=1	264	60	58.3	62.8	Limit: 500uA
MD was connected between GND and enclosure with metal foil					
NC, S1=1, S5=0	264	60	3.9	4.1	Limit: 100uA
NC, S1=1, S5=1	264	60	4.0	4.3	Limit: 100uA
SFC, S1=0, S5=0	264	60	4.3	4.5	Limit: 500uA
SFC, S1=0, S5=1	264	60	4.3	4.5	Limit: 500uA
Fig. 14 - Touch Current (TC)	—	—	Before humidity	After humidity	Measured with non-frequency-weighted device Maximum allowed values: 10 mA NC and SFC
MD was connected between GND and output connector					
NC, S1=1, S5=0	264	60	36.8	43.6	Limit: 10 mA (10000µA)
NC, S1=1, S5=1	264	60	39.8	43.9	Limit: 10 mA (10000µA)
SFC, S1=0, S5=0	264	60	64.4	71.3	Limit: 10 mA (10000µA)
SFC, S1=0, S5=1	264	60	65.8	71.8	Limit: 10 mA (10000µA)
MD was connected between GND and enclosure with metal foil					
NC, S1=1, S5=0	264	60	19.1	20.6	Limit: 10 mA (10000µA)

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Clause	Requirement + Test	Result - Remark	Verdict

Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)		Remarks
NC, S1=1, S5=1	264	60	22.8	23.0	Limit: 10 mA (10000µA)
SFC, S1=0, S5=0	264	60	24.7	27.3	Limit: 10 mA (10000µA)
SFC, S1=0, S5=1	264	60	24.9	27.6	Limit: 10 mA (10000µA)
Fig. 15 - Patient Leakage Current (P)	—	—	—		Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current); 100 µA NC; 500 µA SFC (a.c.) Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current)
Test not conducted.	—	—	—		—
Fig. 16 - Patient leakage current with mains on the F-type applied parts (PM)	—	—	—		Maximum allowed values: Type B: N/A Type BF AP: 5000 µA Type CF AP: 50 µA
Test not conducted.	—	—	—		—
Fig. 17 - Patient leakage current with external voltage on Signal Input/Output part (SIP/SOP)	—	—	—		Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC(d.c. current); 100 µA NC; 500 µA SFC (a.c.) ; Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current)
Test not conducted.	—	—	—		—
Fig. 18 - Patient leakage current with external voltage on metal Accessible Part that is not Protectively Earthed	—	—	—		Maximum allowed values: Type B or BF AP: 500 µA Type CF: N/A
Test not conducted.	—	—	—		—
Fig. 19 – Patient Auxiliary Current	—	—	—		Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current); 100 µA NC; 500 µA SFC (a.c.) ; Type CF AP: 10 µA NC;50 µA SFC (d.c. or a.c. current)
Test not conducted.	—	—	—		—
Fig. 15 and 20 – Total Patient Leakage Current with all AP of same type connected together	—	—	—		Maximum allowed values: Type B or BF AP: 50 µA NC; 100µA SFC (d.c. current); 500 µA NC; 1000 µA SFC (a.c.); Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current)

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Clause	Requirement + Test	Result - Remark	Verdict

Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks
Test not conducted.	—	—	—	—
Fig. 17 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on SIP/SOP	—	—	—	Maximum allowed values: Type B or BF AP: 50 µA NC; 100µA SFC (d.c. current); 500 µA NC;1000 µA SFC (a.c.); Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current)
Test not conducted.	—	—	—	—
Fig. 16 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on F-type AP	—	—	—	Maximum allowed values: Type B: NA Type BF: 5000 µA Type CF: 100 µA
Test not conducted.	—	—	—	—
Fig. 18 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on metal Accessible Part not Protectively Earthed	—	—	—	Maximum allowed values: Type B & BF: 1000 µA Type CF: N/A
Test not conducted.	—	—	—	—
Function Earth Conductor Leakage Current (FECLC)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC
Test not conducted.	—	—	—	—

Supplementary information:

The equipment is a Switch Power Supply for building-in. To be further evaluated in the end use of medical product.

Note 1: For EARTH LEAKAGE CURRENT see 8.7.3 d) and 8.7.4.5;
Note 2: For TOUCH CURRENT see 8.7.3 c) and 8.7.4.6;

Note 3: For PATIENT LEAKAGE CURRENT SEE 8.7.3.b) and 8.7.4.7
Note 4: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS of the same type. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

Note 5: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of Clause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate matter, cleaning & disinfection, & sterilization).

ER - Earth leakage current
TC – Touch current
P - Patient leakage current
PA – Patient auxiliary current
TP – Total Patient current
PM - Patient leakage current with mains on the applied parts
MD - Measuring device

A - After humidity conditioning
B - Before humidity conditioning
1 - Switch closed or set to normal polarity
0 - Switch open or set to reversed polarity
NC - Normal condition
SFC - Single fault condition

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Clause	Requirement + Test	Result - Remark	Verdict

8.8.3	**TABLE: Dielectric strength test of solid insulating materials with safety function – MEANS OF OPERATOR PROTECTION (MOOP) / MEANS OF PATIENT PROTECTION (MOPP)**	**P**

Insulation under test (area from insulation diagram)	**Insulation Type (1 or 2 MOOP/MOPP)**	**Reference Voltage**		**A.C. test voltages in V r.m.s[1)]**	**Dielectric breakdown after 1 minute Yes/No[2)]**
		PEAK WORKING VOLTAGE (U) V $_{peak}$ *1)*	**PEAK WORKING VOLTAGE (U) V d.c.**		
RI - Input to Output - Input to Enclosure	2 MOPP	528	---	4494	No

Supplementary information:

[1] Alternatively, per the Table (i.e., __dc), a d.c. test voltage equal to the peak value of the a.c. test voltage used.

[2] A) Immediately after humidity treatment of 5.7, ME EQUIPMENT de-energized, B) after required sterilization PROCEDURE, ME EQUIPMENT de-energized, C) after reaching steady state operating temperature as during heating test of 11.1.1, and D) after relevant tests of 11.6 (i.e., overflow, spillage, leakage, ingress of water, cleaning, disinfection, and sterilization).

Test performed after humidity preconditioning and heating test and after the fault conditions.

1) The peak working voltage was based on the highest working voltage for worst case consideration.

- End of report -

Attachment 1
Photo



Overall view



Overall view