

## Medical Power Supply Series GTM961005P-\*PD\*\*\*

**Tested under** 

ANSI/ AAMI ES60601-1:2005, ES60601-1:2005/AMD1 1:2012, ES60601-1:2005/AMD 2:2021 CAN/CSA-C22.2 No. 60601-1:14 + A2:22 (R2022) Medical electrical equipment— Part 1: General requirements for basic safety and essential performance IEC 60601-1-6 Edition 3.2 2020-07 CAN/CSA-C22.2 NO. 60601-1-6:11 + A1:15 + A2:21 (R2021) Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability ANSI/ AAMI HA60601-1-11:2015 [Including AMD1: 2021] CSA C22.2 NO. 60601-1-11:15 (R2020) + A1:21 Medical Electrical Equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral Standard: Requirements for medical electrical equipment and medical electrical equipment and medical electrical systems used in the home healthcare environment

File: E115461

MET Report: 128984

Approved: Nov. 10, 2023

### **Applicant:**

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### **Prepared By:**

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## **Table of Contents**

CHANGE RECORD	3
DESCRIPTION	4
MARKINGS	11
MANUAL/SERVICE INSTRUCTIONS	13
ALTERNATE LISTEE INFORMATION	14
APPLICANT'S RESPONSIBILITIES	15
PRODUCT MODIFICATIONS: Manufacturing and Production-Line Tests and Documentation performed by Manufacturer	15 17
CRITICAL COMPONENTS	18
CRITICAL DRAWINGS	27
FIGURES	28
CONCLUSION	44





## **Change Record**

Change Number	Description	Approval Date	Project Number	Amendment Engineer	Engineer Initials
	None				

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MET Report: NRTLC128984

## Description

### Product(s) Covered:

• Power Supply,

GTM961005P-\*PD\*\*\*

The 1st "\*" =1 to 100, with interval of 1, denoting the rated output wattage designation from 1 W to 100 W.

The 2nd "\*"= -USBCJ means USB Type-C jack in housing

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= -USBCP means USB Type-C plug on fixed cord with strain-relief in housing

The 3rd "\*"= -T2 means desktop class II with C8 AC inlet

= -T2A means desktop class II with C18 AC inlet

- = -T3 means desktop class I with C14 AC inlet
- = -T3A means desktop class I with C6 AC inlet

The 4th "\*" denotes any six character = 0-9 or A-Z or ()[] or – or blank for marketing purposes.

### **Product Description:**

• The equipment is external desktop AC-DC switching mode power supply with type C USB power delivery supporting protocol (PD) 2.0/3.0 + PPS, with max. output power 100 W, for MED use.





#### **Model Differences:**

- All models are identical except for:
  - 1. Rated output power, which is set by firmware; 2. The following differences:

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2. The lo	DOP	uniterences.			0	h.	0
	PCB	Applian	Earthing type		Output	Jutput	Outpu
	layou	ce inlet		Output	Voltage	Curren	t
Model	t	and		connecti		t	Power
Widdei		Class of		on			
		equipme		on			
		nt					
GTM961005P-		C8,	F1				
*PD-USBCJ-T2*		Class II					
GTM961005P-		C10					
*PD-USBCJ-		C18,					
T2A*		Class II					
			F2	USB			
		<b>C14</b>	L	Type-C			
GTM961005P-		C14,		jack in			
*PD-USBCJ-T3*		Class I	E R R	housing			
				8			
			E1				
GTM961005P-		C6			PD mode:		
*PD-USBCJ-		Class I			5.0 -20.0 V		
T3A*		C1055 1	E		PPS mode:		
GTM961005P-	The		F1		3.3-21.0 V	Max.	Max.
	same	C8,	L		PD+PPS	5.0A	100W
TD-USDCF-		Class II			mode: 5.0 -		
$\frac{12^{v}}{\text{CTMO(1005D)}}$				LICD	20.0 V and		
GIM961005P-		C18,			3.3 -21.0 V		
*PD-USBCP-		Class II		Type-C			
12A*				plug on			
CTM061005D			F2	fixed			
*DD USDCD		C14,		cord			
TD-USDCP-		Class I		with			
13*				strain-			
			or	relief in			
GTM961005P-		00	El	housing			
*PD-USBCP-		$C_{0},$					
T3A*		Class I					
			£				

The bold lines in drawings of earthing type represent protective earthing.

#### **Electrical Rating:**

- Input: 100-240 V~, 50-60 Hz, 1.5 A
- Output: PD mode: 5.0 20.0 V===, Max. 5 A, Max. 100 W
- PPS mode: 3.3 21.0 V===, Max. 5 A, Max. 100 W
- PD+PPS mode: 5.0 20.0 V=== and 3.3 21.0 V===, Max. 5 A, Max. 100 W





### Engineering Considerations (Not For Field Representative's Use):

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- The Power Supplies, Series GTM961005P-\*PD\*\*\*, has been investigated in accordance with ANSI/ AAMI ES60601-1:2005, ES60601-1:2005/AMD1 1:2012, ES60601-1:2005/AMD2:2021, and CAN/CSA-C22.2 NO. 60601-1:14 + A2:22 (R2022), Medical electrical equipment— Part 1: General requirements for basic safety and essential performance; IEC 60601-1-6 Edition 3.2 2020-07 and CAN/CSA-C22.2 NO. 60601-1-6:11 + A1:15 + A2:21 (R2021) Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability; ANSI/ AAMI HA60601-1-11:2015 [Including AMD1: 2021], CSA C22.2 NO. 60601-1-11:15 (R2020) + A1:21 Medical Electrical Equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral Standard: Requirements for medical electrical equipment and medical electrical equipment and medical electrical systems used in the home healthcare environment with the following considerations:
  - 1 Exceptions:

The following clauses are not evaluated in this report:

Clause 11.7 Biocompatibility, referencing ISO 10993

Clause 17 EMC, referencing IEC 60601-1-2

- 2 Scope of power supply evaluation defers the following clauses to be determined as part of the endproduct evaluation:
  - Clause 7.5 Safety signs,
  - Claus 7.9 Accompany Documents,
  - Clause 9 ME hazard, except 9.1 and 9.3 are evaluated,
  - Clause 10 Radiation,
  - Clause 14 PEMS,
  - Clause 16 ME system,
  - Risk management was excluded from this evaluation.

3 Risk control/Engineering considerations for component power supply:

For power supplies with no Risk Management installed in an end-product, consideration must be given to the following:

- a) End-product Risk Management Process to include consideration the acceptability of risk for the following components that were identified as High-Integrity Component: i.e. Fuse (F1, F2).
- b) End-product Risk Management Process to include consideration the need for simultaneous fault condition testing.
- c) Power supply tested in 25°C, 95% R.H., 168 h. End-product Risk Management Process to include consideration the acceptability criteria.
- d) End-product Risk Management Process to include consideration the acceptability of risk in conjunction to insulation to resistance to heat, moisture, and dielectric strength.
- e) End-product Risk Management Process to include consideration the acceptability of risk in conjunction to the movement of components or conductors as part of the power supply.
- f)End-product Risk Management Process to include consideration the acceptability of risk in conjunction to the routing of wires away from moving parts and sharp edges as part of the power supply.
- g) End-product Risk Management Process to include consideration the acceptability of risk in conjunction to the Cleaning and Disinfection Methods as part of the power supply.
- h) End-product Risk Management Process to include consideration the acceptability of risk in conjunction to the Leakage of Liquids as part of the power supply.
- i)End-product Risk Management Process to include consideration the acceptability of risk in conjunction to the Arrangement of Indicators as part of the power supply.





j)End-product Risk Management Process to include consideration the acceptability of risk in conjunction to the results of Mechanical Testing conducted as part of the power supply.

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- k)End-product Risk Management Process to include consideration the acceptability of risk in conjunction to the selection of components as it pertains to the intend use, essential performance, transport, storage conditions as part of the power supply.
- This product must be installed in accordance with all codes applicable to the location of the installation and in accordance with its instructions for use.



MET Report: NRTLC128984

### **Description (Continued)**

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### Note to Field Representative:

• A sample of each component listed below and a purchase order for the work described below at the current hourly rate shall be submitted to:\*

#### **Eurofins E&E NA, Inc.** 914 West Patapsco Avenue Baltimore, Maryland 21230-3432

for reassessment processed under job # for verification of construction against the associated drawings also listed below. The component(s) shall be subjected to an annual audit by MET for continued compliance. The annual re-verification is a client incurred expense to be assessed at the current hourly rate at the time of the test. The estimated time for re-verification is also listed below.

Figure/ Item #	Component	Controlled Document Number	Re-Verification Type	Estimated Time
5,9/8	Transformer	TF131	Dimension - See Illustration 7, and Electric strength test	2 h

\*Alternatively: If the evaluation is performed by the MET representative's lab other than the location above or by the MET representative during the Follow-up inspection, all data shall be returned to the Baltimore office listed above for surveillance tracking under the assigned job number mentioned above.

• The above inspections are a client incurred cost and will be billed at the hourly rate in place at the time of the inspection.





## **General Requirements**

<u>Scope of Requirements</u>: The requirements contained within this section apply to all products contained within this Follow-Up Service Report File where applicable.

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Term	Definitions
SELV:	Safety Extra Low Voltage
PCB:	Printed Circuit Board
Listed/Recognized Component:	A component evaluated to the applicable U.S. standards by a Nationally
	Recognized Testing Laboratory (NRTL).
Certified Component:	A component evaluated to the applicable Canadian standards by a
	Certification Organization (CO).
Listee:	Applicant

**Definitions:** (as defined or used in the context of the standard)

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<u>Measurements</u>: All dimensions indicated in the body of this report are approximations unless otherwise indicated.

<u>Corrosion Protection</u>: All corrosive metals shall be provided with a means to protect from corrosion. Acceptable methods include painting, plating and galvanizing. Dissimilar metals shall not be employed where reliable continuity is required.

<u>Soldered Connections</u>: All soldered connections shall be made mechanically secure before soldering. Tack soldering is not acceptable. Acceptable forms of mechanical securement include:

- A) Lead is inserted through an eyelet or opening of a terminal block prior to soldering.
- B) Lead is inserted into a U or V shaped slot in the terminal prior to soldering.
- C) Lead is wrapped around a terminal post prior to soldering.
- D) Lead is tied to adjacent lead with wire tie-wrap near termination point.

**Electrical Connections:** All electrical connections other than soldering shall be provided with positive detent, crimp type insulated Recognized Component connectors suitable for the voltage and temperatures involved. They shall be sized for the wire and mounting terminations. Where hazardous voltage or energy is involved, all wire connections to connectors shall employ a recognized method of double securement. Where fork-type lugs are used, they shall be snap-on or up-turned lug type.

<u>Mechanical Assembly</u>: All parts shall be secured by welding, bolts/nuts with lock or star washers, or thread forming screws.

<u>Creepage and Clearances:</u> Shall be in accordance with the evaluated product standards.





### **General Requirements (Continued)**

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### Where present, the following items are required.

Internal Plastics: Shall be a Recognized/Certified Component, Plastic, rated minimum HB/5VA.

PCB: Shall be a Recognized Component, rated minimum 94V-2 and 130°C.

**<u>Tubing and Sleeving</u>**: Shall be a Listed/Recognized/Certified Component, rated minimum 300V, 75°C minimum, VW-1, unless otherwise noted.

<u>Wire Connectors</u>: (Various crimp-type) Shall be Listed/Recognized/Certified Components sized for the wire and mounting terminations. Both the wire insulation and the conductor shall be crimped.

**Fuseholder:** Operator accessible fuseholders, when provided, are connected to the ungrounded conductor(s) of the primary circuit.

**Internal Wiring:** All internal wiring and connections are properly jacketed or enclosed within the equipment. Wiring is routed and secured to reduce the possibility of stress being transmitted to electrical connections, as necessary. All internal conductors in the secondary circuits are routed away from primary circuit conductors and from uninsulated live parts. There is no internal wiring subject to contact by the user when the product is employed as intended. The internal wiring is acceptable for conditions of service to which it will be subjected. Internal conductors consist of Recognized Component AWM insulated individual conductors; sized in accordance with the National Electric code and Canadian Electrical code, as may be applicable for the current expected in the conductor, rated 300V, 80°C, 24-18AWG.

**Interconnecting Cords and Cables:** Flexible telecommunication cord and cable assemblies employed for interconnection between components are to be rated for and comply with temperatures, exposure to oil or grease and other conditions of service within the environment the product is to be utilized.





### Markings

Etching, molding, die-stamping, silk-screening, stamped-, or etched-metal labels secured by rivets or screws are considered permanent. Recognized/Certified Component, Marking and Labeling Systems, and/or labels tested and deemed suitable for the surface to which it is applied is also considered permanent. Per the Canadian Electrical Code described in CSA C22.0 General Requirements, Canadian product certification requires warning/cautionary markings in both English and French languages. It is the Applicant's responsibility to provide the listed Bilingual Markings shown below in accordance with the Canadian regulatory requirements. Each product is to be permanently marked with the following information:

- a. The MET Mark (refer to MET Applicant Contract), with the applicant/listee name or alternate listee name as identified within this report, trade name or trade mark, product model number, and a date of manufacture or serial number. If the date of manufacture is in a code, it shall not repeat in less than 10 years and it shall not require reference to the manufacturer's records to determine when the product was manufactured.
- b. Method of applying the MET Mark:
  Direct Imprinting
  Purchasing Labels from MET Laboratories, Inc. Approved MET Mark:



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c. For Mains Connected Equipment, a rating label adjacent to the inlet connector identifying the voltage, current or power, frequency for the equipment.



GlobTek<sup>®</sup>, Inc.

5.0V \_\_\_\_ 5.0A

9.0V \_\_\_\_ 5.0A

15.1V === 5.0A

20.0V === 5.0A

3.3-21.0V \_\_\_\_ 5.0A

ICT/ITE/Medical Power supply/电源供应器

INPUT/вход/输入:100-240V~, 50-60Hz, 1.5A

ins Dr le, NJ 07647 USA tek.com

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File Number: E115461

REF P/N/Homep/料号:





(Class I model)

Ta=40°C

IP22

A1, A12, B1, B12: GND

中国制造

A4, A9, B4, B9: V+ CC1: A5 D+: A6 EFF

D-: A7

000158101/07

SN 000150101

(Class II model)





### **Manual/Service Instructions**

- Operations and Service instructions are provided with the equipment.
- See illustration 1 to 3.





## **Alternate Listee Information**

Alternate listees and product names or model numbers: None

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## **Applicant's Responsibilities**

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### **Product Modifications:**

Minor product modifications by the manufacturer may be allowed using the following guidelines:

1. Components identified in this report as "Listed, Recognized, or Certified" and **NOT** identified with a manufacturer name or part number may be exchanged with an alternate "Listed, Recognized, or Certified" component of equivalent value.

*Example:* <u>Appliance Inlet Connector</u> - Listed/Certified Component, IEC 320 style male connector, rated 250 volts and 20 amperes. Mechanically secured to the front panel with screws and locking washers.

- This inlet connector may be replaced with any Listed/Certified inlet connector with the same ratings as stated and where mechanical securement is maintained.
- 2. Components identified by a manufacturer name, part number, or with specific comments, (such as AC only, indoor use only, approved for use in this product only), may **NOT** be replaced or modified without prior approval from MET Laboratories.

*Example:* <u>Circuit Breaker</u> - Recognized/Certified Component, ABCD Co. P/N XYZ123, rated 250 volts maximum, 50/60 Hz, 25 full-load amperes, 31.3 trip amperes. Toggle handle marked with IEC on/off symbols. Mechanically secured to the front panel with screws and locking washers.

• This circuit breaker can **NOT** be modified or changed without prior approval by MET Laboratories, Inc.





## **Applicant's Responsibilities (Continued)**

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#### **Project Amendments:**

For any changes related to product construction, manufacturing locations, if the product is intended to be marketed/sold under an alternate name or model number than that originally listed, or any issues which would require notification or change in the status of this file, please complete the form and return to Eurofins E&E NA following the instructions provided on the form.

For your convenience a Project Amendment Request (PAR) form is available for download at http://corp.metlabs.com/safetyreq/ Alternatively, please provide it to your local Eurofins office or Eurofins Partner Representative.

If you are terminating or temporarily suspending production of this product for an extended period, please send a letter on company letterhead to:

Eurofins E&E NA, Inc. Attn: Follow Up Services Department 914 West Patapsco Avenue Baltimore, Maryland 21230 USA Fax: (410) 354-3313



MET Report: NRTLC128984

## **Applicant's Responsibilities (Continued)**

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# Manufacturing and Production-Line Tests and Documentation performed by Manufacturer.

All certified products are required to be subjected to production line testing as indicated below:

### Dielectric Voltage-Withstand Test:

Each complete end product shall be capable of withstanding, without electrical breakdown, the application of a continuous sinusoidal or direct current voltage between uninsulated live parts and accessible dead metal parts that are likely to become energized in accordance with the following method.

Circuit Rating	Component Tested	Circuit Tested	Voltage (VAC)	Voltage (VDC)	Time (sec)
100 to 240 V	Main unit	Primary circuit to output port (earthing type F1 and F2)	4000		1
100 to 240 V	Main unit	Primary circuit to enclosure	4000		1
100 to 240 V	Main unit	Primary circuit to Earthing	1500		1

#### Grounding Continuity Test:

Each complete product shall be tested to determine grounding continuity between the grounding pin or terminal of the attachment plug and the accessible dead metal parts that are likely to become energized. The grounding contact of each receptacle, and other means for grounding on the load side, shall be included in this test. Compliance is to be determined by any appropriate device, such as an ohmmeter, or a battery and buzzer combination, applied between the points under test.

### Documentation:

The manufacturer is required to record the production line test results. The data recorded is to include the type of test, date of test, serial number of the product, indications of pass, fail, or retest, test equipment utilized, calibration date of test equipment utilized, and the initials or signature of the test technician. Test records shall be required to be maintained from factory follow-up audit to factory follow-up audit and must be available for the inspectors' review. Records may be in the form of travelers, logs, computer files, or other such suitable documentation method.





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## **Critical Components**

Figure /	Object/ Parts	Manufacturer/Trade	Type/ Model	Technical Data	Standard	Mark(s) of	Secured Method
itelli No.			DB-6	2.5.4. 25014	$\frac{1}{10000000000000000000000000000000000$		Soldered
	AC inlet for	LECI		2.5A, 250Vac	01 00320 1	Listed	on PCB
	Class I models	Electronics Co.,		Standard sheet:		(E302229)	and
	(C6 type)	Ltd.		6			secured by enclosure
	Alternative	Rich Bay Co	R-30790	2.5A, 250Vac	UL 60320-1	UL/CSA	
		Ltd.		Standard sheet		Listed	
				C6		(E184638)	
	Alternative	Sun Fair Electric	S-02	2.5A, 250Vac	UL 498	UL/CSA	
		Wire & Cable		Standard sheet:		Listed (E226643)	
5/1		(HK)Co. Ltd		C6		(1220013)	
5/1	Alternative	TECX-UNIONS	TU-333	2.5A, 250Vac	UL 60320-1	UL/CSA	
		Technology	series	Standard sheet:		(E220004)	
		Corporation		C6			
	Alternative	Rong Feng	RF-190	2.5A, 250Vac	UL 60320-1	UL/CSA	
		Industrial Co		Standard sheet:		Recognized	
		Ltd.		C6		(E102041)	
	Alternative	ZHE JIANG BEI ER	ST-A04-	2.5A, 250Vac	UL 60320-1	UL/CSA	
		JIA ELECTRONIC	001,	Standard sheet:		Recognized (E225980)	
		COLID	ST-A04-	C6		(1223)00)	
		LECI	002	104 0501	LH (0220-1		0.11.1
	AC inlet for Class I	Electronics Co	DB-14	Standard sheet:	UL 60320-1	UL/CSA Recognized	soldered on PCB
	models	Ltd.		C14		(E302229)	and
	(C14 type)						secured by
	Alternative	Rich Bay Co.,	R-301SN	10A, 250Vac	UL 60320-1	UL/CSA	cherosure
		Ltd.		Standard sheet:		recognized (E184638)	
				C14		(1104050)	
<b>T</b> (1	Alternative	Sun Fair Electric	S-03	10A, 250Vac	UL 498	UL/CSA Bacognized	
5/1		Wire & Cable		Standard sheet:		(E226643)	
		(HK)Co. Ltd.		C14			
	Alternative	TECX-UNIONS	TU-301-S,	10A, 250Vac	UL 60320-1	UL/CSA Recognized	
		Technology	TU-301-SP	Standard sheet:		(E220004)	
		Corporation		C14			
	Alternative	Rong Feng	SS-120	10A, 250Vac	UL 60320-1	UL/CSA Recognized	
		Industrial Co.,		Standard sheet:		(E102641)	
		Ltd.		C14			





## **Critical Components**

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Figure / item No.	Object/ Parts No.	Manufacturer/Trade mark	Type/ Model	Technical Data	Standard (Edition / year)	Mark(s) of Conformity	Secured Method
	Alternative	ZHE JIANG BEI ER JIA ELECTRONIC CO LTD	ST-A01- 001L ST- A01-002L ST-A01- 003J ST- A01-003K	10A, 250Vac Standard sheet: C14	UL 60320-1	UL/CSA Recognized (E225980)	
	Appliance inlet for Class II model (C8 type)	LECI Electronics Co., Ltd.	DB-8	2.5A, 250Vac Standard sheet: C8	UL 60320-1	UL/CSA Recognized (E302229)	Soldered on PCB and secured by enclosure
	Alternative	Rich Bay Co., Ltd.	R- 201SN90	2.5A, 250Vac Standard sheet: C8	UL 60320-1	UL/CSA Recognized (E184638)	
5/1	Alternative	Sun Fair Electric Wire & Cable (HK)Co. Ltd.	S-01	2.5A, 250Vac Standard sheet: C8	UL 498	UL/CSA Recognized (E226643)	
	Alternative	TECX-UNIONS Technology Corporation	SO-222 series	2.5A, 250Vac Standard sheet: C8	UL 60320-1	UL/CSA Recognized (E220004)	
	Alternative	Rong Feng Industrial Co., Ltd.	RF-180	2.5A, 250Vac Standard sheet: C8	UL 60320-1	UL/CSA Recognized (E102641)	
	Alternative	ZHE JIANG BEI ER JIA ELECTRONIC CO LTD	ST-A03- 008B, ST-A03- 005	2.5A, 250Vac Standard sheet: C8	UL 60320-1	UL/CSA Recognized (E225980)	
5/1	Appliance inlet for Class II model	Rong Feng Industrial Co., Ltd	SS-120	10A, 250V	UL 60320-1	UL/CSA Recognized (E102641)	Soldered on PCB and secured by enclosure
	(C18 type) Alt.	HCR ELECTRONICS CO., LTD	SK05	10A, 250V	UL 60320-1	UL/CSA Recognized (E344254)	
3/2	РСВ	GUANGDE BOYA XINXIANG ELECTRONIC TECHNOLOGY CO LTD	BY-1	Min. V-0, min 1.6 mm thickness, 130°C	UL 796 UL 94	UL/CSA Recognized (E475783)	Secured by enclosure





## **Critical Components**

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Figure / item No.	Object/ Parts No.	Manufacturer/Trade mark	Type/ Model	Technical Data	Standard (Edition / year)	Mark(s) of Conformity	Secured Method
	Alternative	SHUANG MING INDUSTRY CO LTD	T005V0, T015V0	Min. V-0, min 1.6 mm thickness, 130°C	UL 796 UL 94	UL/CSA Recognized (E78017)	
	Alternative	JIANGXI ZHONG XIN HUA ELECTRONICS INDUSTRY CO LTD	ZXH-1, ZXH-2	Min. V-0, min 1.6 mm thickness, 130°C	UL 796 UL 94	UL/CSA Recognized (E331298)	
	Alternative	SHENZHEN JIA LI CHUANG TECHNOLOGY DEVELOPMENT CO LTD	JLC-1, JLC-2	Min. V-0, min 1.6 mm thickness, 130°C	UL 796 UL 94	UL/CSA Recognized (E479892)	
	Alternative	Interchangeable	Interchange able	Min. V-0, min 1.6 mm thickness, 130°C	UL 796 UL 94	UL/CSA Recognized	
	Fuse (F1, F2) (F2 is optional for Class II models)	Conquer Electronics Co., Ltd.	MST	T3.15A, 250V	ANSI/UL 248- 1, CSA-C22.2 No. 248.1	UL/CSA Recognized (E82636)	Soldered on PCB
5/3	Alternative	Suzhou Walter Electronic Co., Ltd.	2010	T3.15A, 250V	ANSI/UL 248- 1, CSA-C22.2 No. 248.1	UL/CSA Recognized (E56092)	
	Alternative	Bel Fuse Ltd.	RST	T3.15A, 250V	ANSI/UL 248- 1, CSA-C22.2 No. 248.1	UL/CSA Recognized (E20624)	
	Alternative	Conquer Electronics Co., Ltd.	MET	T3.15A, 250V	ANSI/UL 248- 1, CSA-C22.2 No. 248.1	UL/CSA Recognized (E82636)	
	X capacitor (CX1) (optional)	Cheng Tung Industrial Co., Ltd.	СТХ	X1 or X2, AC310V, 110 °C Max. 0.47µF,	ANSI/UL6038 4-14	UL/CSA Recognized (E193049)	Soldered on PCB
	Alternative	Tenta Electric Industrial Co. Ltd.	MEX	X1 or X2, AC275V, 100 °C Max. 0.47µF,	ANSI/UL6038 4-14	UL/CSA Recognized (E222911)	
5/4	Alternative	Ultra Tech Xiphi Enterprise Co. Ltd.	HQX	X1 or X2, AC275V, 110 °C Max. 0.47µF,	ANSI/UL6038 4-14	UL/CSA Recognized (E183780)	
	Alternative	Dain Electronics Co., Ltd.	MPX, MEX, NPX	X1 or X2, AC275V, 110 °C Max. 0.47µF,	ANSI/UL6038 4-14	UL/CSA Recognized (E147776)	





## **Critical Components**

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Figure / item No.	Object/ Parts No.	Manufacturer/Trade mark	Type/ Model	Technical Data	Standard (Edition / year)	Mark(s) of Conformity	Secured Method
	Alternative	Shantou High-New Technology Dev.Zone Songtian Enterprise Co., Ltd.	MPX	X1 or X2, AC275V, 110 °C Max. 0.47µF	ANSI/UL6038 4-14	UL/CSA Recognized (E208107)	
	Varistor (MOV1) (optional)	Xiamen Set Electronics Co.,Ltd	TFV8S471 K	Max. Continuous voltage: 300Vac(rms), Min. 105°C, The coating is Min. V-0	UL 1449	UL/CSA Recognized (E322662)	Soldered on PCB
5/5	Alternative	SHANTOU HIGH- NEW TECHNOLOGY DEVELOPMNT ZONE SONGTIAN ENTERPRISE CO LTD	10D621K	Max. Continuous voltage: 385Vac(rms), Min. 125°C, The coating is Min. V-0	UL 1449	UL/CSA Recognized (E330837)	
	Alternative	Guangdong Huiwan Electronics Technology Co.Ltd.	V-621K-10 DEH	Max. Continuous voltage: 385Vac(rms), Min. 125°C, The coating is Min. V-0	UL 1449	UL/CSA Recognized (E480104)	
	Optocoupler (U4)	LITE-ON Technology Corporation	LTV-10xx	Ext. Cr: min. 8.0 mm; Ext. Cl: min. 8.0mm; Max. operating temp.: 115°C	UL 1577	UL/CSA Recognized (E113898)	Soldered on PCB
6/6	Alternative	Everlight Electronics Co., Ltd.	EL1019	Ext. Cr: min. 8.1 mm; Ext. Cl: min. 8.1mm; Max. operating temp.: 110°C	UL 1577	UL/CSA Recognized (E214129)	
	Alternative	VISHAY Semiconductor GmbH	TCLT1019	Ext. Cr: min. 8.0 mm; Ext. Cl: min. 8.0mm; Max. operating temp.: 110°C	UL 1577	UL/CSA Recognized (E132473)	
-/7	PFC Choke (L2)	GlobTek/HAOPUW EI/HEJIA/BOAM	LF060	Min.130°C	AAMI ES 60601-1 CSA C22.2 No. 60601-1	Unlisted component	Soldered on PCB





## **Critical Components**

E&E

Figure / item No.	Object/ Parts	Manufacturer/Trade mark	Type/ Model	Technical Data	Standard (Edition / year)	Mark(s) of Conformity	Secured Method
5.0/0	Transformer	GlobTek/ HAOPUWEI/	TF131	Class B	AAMI ES 60601-1	Unlisted component	Soldered on PCB
5,9/8	(11)	BOAM			CSA C22.2 No. 60601-1	1	
	-Insulation system	GLOBTEK INC	GTX-130- TM	Class 130(B)	UL 1446	UL/CSA Recognized (E243347)	Fixed inside transform
	Alternative	WUXI HAOPUWEI ELECTRONICS CO LTD	ZT-130	Class 130(B)	UL 1446	UL/CSA Recognized (E315275)	er
	Alternative	SHAN DONG BOAM ELECTRIC CO LTD	BOAM-01, B1	Class 130(B)	UL 1446	UL/CSA Recognized (E252329)	
	-Primary winding	NINGBO JINTIAN NEW MATERIAL CO LTD	2UEW	MW 75C, min.130°C	UL 1446	UL/CSA Recognized (E227047)	Fixed inside transform
	Alternative	SHENZHEN DAYANG INDUSTRY CO LTD	2UEW	MW75-C, Min.130°C	UL 1446	UL/CSA Recognized (E176101)	er
	Alternative	WUXI JUFENG COMPOUND LINE CO LTD	2UEW, 2UEWB	MW75#, min.130°C	UL 1446	UL/CSA Recognized (E206882)	
	Alternative	ZHEJIANG LANGLI ELECTRIC EQUIPMENTS CO LTD	UEW	MW 79-C, min.130°C	UL 1446	UL/CSA Recognized (E222214)	
	Alternative	JIANGSU DARTONG M&E CO.,LTD	2UEW	MW 75-C, min.130°C	UL 1446	UL/CSA Recognized (E237377)	
	Alternative	SHANDONG SAINT ELECTRIC CO LTD	2UEW	MW75#, min.130°C	UL 1446	UL/CSA Recognized (E194410)	
	Alternative	Interchangeable	Interchange able	Min.130 °C	UL 1446	UL/CSA Recognized	
	-Triple- insulated wire (Secondary)	GREAT LEOFLON INDUSTRIAL CO LTD	TRW(B)	Min.130°C	UL 2353	UL/CSA Recognized (E211989)	Fixed inside transform er
	Alternative	KBI COSMOLINK CO LTD	TIW-M	Min.130°C	UL 2353	UL/CSA Recognized (E213764)	
	Alternative	FURUKAWA ELECTRIC CO LTD	TEX-E	Min.130°C	UL 2353	UL/CSA Recognized (E206440)	





## **Critical Components**

E&E

Figure / item No.	Object/ Parts No.	Manufacturer/Trade mark	Type/ Model	Technical Data	Standard (Edition / year)	Mark(s) of Conformity	Secured Method
	Alternative	TOTOKU INC.	TIW-2	Min.130°C	UL 2353	UL/CSA Recognized (E166483)	
	Alternative	HOI LUEN ELECTRICAL MFR CO LTD	THL-F-xx, THL-F-SB- xx,	Min.130°C	UL 2353	UL/CSA Recognized (E257525)	
	-Bobbin	CHANG CHUN PLASTICS CO LTD	T375J, T375HF	V-0, 150°C,	UL 94 UL 746 A/B/C/D	UL/CSA Recognized (E59481)	Fixed inside transform er
	Alternative	SUMITOMO BAKELITE CO LTD	PM-9820	V-0, 150°C,	UL 94 UL 746 A/B/C/D	UL/CSA Recognized (E41429)	
	Alternative	Resonac Corporation	CP-J-8800	V-0, 150°C,	UL 94 UL 746 A/B/C/D	UL/CSA Recognized (E42956)	
	Alternative	CHUANG CHUN PLASTICS CO LTD	4130	V-0, 150°C,	UL 94 UL 746 A/B/C/D	UL/CSA Recognized (E59481)	
	-Insulating tape	3M COMPANY	1350F-1, 1350T-1, 44	Min.130°C	UL 510	UL/CSA Recognized (E17385)	
	Alternative	BONDTEC PACIFIC CO LTD	370S	Min.130°C	UL 510	UL/CSA Recognized (E175868)	
	Alternative	JINGJIANG YAHUA PRESSURE SENSITIVE GLUE COLTD	PZ, CT, WF	Min.130°C	UL 510	UL/CSA Recognized (E165111)	
	Alternative	JINGJIANG JINGYI ADHESIVE PRODUCT CO LTD	JY25-A	Min.130°C	UL 510	UL/CSA Recognized (E246950)	
	Alternative	CHANG SHU LIANG YI TAPE INDUSTRY CO LTD	LY-XX	Min.130°C	UL 510	UL/CSA Recognized (E246820)	





## **Critical Components**

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Figure / item No.	Object/ Parts No.	Manufacturer/Trade mark	Type/ Model	Technical Data	Standard (Edition / year)	Mark(s) of Conformity	Secured Method
5/9	Insulating tube for earthing wire	SHENZHEN WOER HEAT- SHRINKABLE MATERIAL CO LTD	RSFR, RSFR-H, RSFR- HPF, WF	600V, 125°C	UL 224	UL/CSA Recognized (E246820)	Fixed on bonding wire
	Alternative	QIFURUI ELECTRONICS CO	QFR-h	600V, 125°C	UL 224	UL/CSA Recognized (E203950)	
	Alternative	DONGGUAN SALIPT CO LTD	SALIPT S- 901-300, SALIPT S- 901-600	Min. 300V, 125°C	UL 224	UL/CSA Recognized (E225897)	
	Alternative	GUANGZHOU KAIHENG ENTERPRISE GROUP	K-2 (+), K-2 (CB)	Min. 300V, 125°C	UL 224	UL/CSA Recognized (E209436)	
	Alternative	CHANGYUAN ELECTRONICS (SHENZHEN) CO LTD	CB-HFT CB-TT-T, CB-TT-S	Min. 300V, 125°C	UL 224	UL/CSA Recognized (E214175)	
3/10	Enclosure	SABIC JAPAN L L C	945(GG)	Min.V-0, 120°C, Min. 2.0 mm	UL 94 UL 746 A/B/C/D	UL/CSA Recognized (E207780)	Ultrasonic soldered together
	Alternative	SABIC INNOVATIVE PLASTICS B V	945(GG)	Min.V-0, 120°C, Min. 2.0 mm	UL 94 UL 746 A/B/C/D	UL/CSA Recognized (E45329)	
5/11	Bonding wire for Class I model	KUNSHAN NEW ZHICHENGELECT RONICS TECHNOLOGIE S CO LTD	1815, 1015, 1007	Min. 20 AWG, Min.300V, Min. 80°C Min. VW-1	UL 758	UL/CSA Recognized (E237831)	Soldered and fixed by glue on PCB and appliance inlet
	Alternative	ZHUANG SHAN CHUAN ELECTRICAL PRODUCTS (KUNSHAN) CO LTD	1815, 1015, 1007	Min. 20 AWG, Min.300V, Min. 80°C Min. VW-1	UL 758	UL/CSA Recognized (E333601)	





## **Critical Components**

E&E

Figure / item No.	Object/ Parts No.	Manufacturer/Trade mark	Type/ Model	Technical Data	Standard (Edition / year)	Mark(s) of Conformity	Secured Method
	Alternative	Suzhou Jiahuishu Electronic Co Ltd	1815, 1015, 1007	Min. 20 AWG, Min.300V, Min. 80°C Min. VW-1	UL 758	UL/CSA Recognized (E353532)	
	Alternative	GlobTek, Inc.	1815, 1015, 1007	Min. 20 AWG, Min.300V, Min. 80°C Min. VW-1	UL 758	UL/CSA Recognized (E464257)	
	Alternative	Various	1815, 1015, 1007	Min. 20 AWG, Min.300V, Min. 80°C Min. VW-1	UL 758	UL/CSA Recognized (E45329)	
5/12	Y-Capacitor (CY1, CY2) (optional)	SUCCESS ELECTRONICS CO LTD	SE,	max. 2200pF min.250ac min.125°C type Y1	ANSI/UL6038 4-14	UL/CSA Recognized (E114280)	Soldered on PCB
	Alternative	SUCCESS ELECTRONICS CO LTD	SB	max. 2200pF min.250ac min.125°C type Y1	ANSI/UL6038 4-14	UL/CSA Recognized (E114280)	
	Alternative	Shantou High-New Technology Dev.Zone Songtian Enterprise Co., Ltd.	CD	max. 2200pF min.250ac min.125°C type Y1	ANSI/UL6038 4-14	UL/CSA Recognized (E208107)	
	Alternative	MURATA MFG CO LTD	KX	max. 2200pF min.250ac min.125°C type Y1	ANSI/UL6038 4-14	UL/CSA Recognized (E37921)	
	Alternative	TDK CORP	CD	max. 2200pF min.250ac min.125°C type Y1	ANSI/UL6038 4-14	UL/CSA Recognized (E37861)	
/13	Marking plate	GlobTek		Permanently secured Engraving or Silkscreen or Laser printing	UL 62368-1	Tested with equipment	Sticked to enclosure surface





## **Critical Components**

E&E

Figure / item No.	Object/ Parts No.	Manufacturer/Trade mark	Type/ Model	Technical Data	Standard (Edition / year)	Mark(s) of Conformity	Secured Method
	Alternative	FAN JA PAPER PRINTING CO LTD	FJ-03-3 FJ-07 FJ10	Rated min 80 °C	UL 969	UL/CSA Recognized (MH19546 )	
	Alternative	SUZHOU HAIRONG PACKING PRODUCTION CO LTD	HR-01 HR-04 HR-05	Rated min 80 °C	UL 969	UL/CSA Recognized (MH48692 )	
	Alternative	DONGGUAN XIANGQUAN PRINTING CO LTD	XQ03	Rated min 80 °C	UL 969	UL/CSA Recognized (MH27594 )	
	Alternative	ZHONGSHAN ZHANTU PRINTING CO LTD	ZT969-1, ZT969-2, ZT969-3	Rated min 80 °C	UL 969	UL/CSA Recognized MH47528	
	Alternative	Interchangeable	Interchange able	Rated min 80 °C	UL 969	UL/CSA Recognized	
1/14	Output cord	KUNSHAN NEW ZHICHENG ELECTRONICS TECHNOLOGIES CO LTD	2725	Min. 28AWG, Min.30V, Min. 60°C Min. VW-1	UL 758	UL/CSA Recognized (E37831)	Soldered on PCB, then fixed by enclosure
	Alternative	ZHUANG SHAN CHUAN ELECTRICAL PRODUCTS (KUNSHAN) CO LTD	2725	Min. 28AWG, Min.30V, Min. 60°C Min. VW-1	UL 758	UL/CSA Recognized (E333601)	
	Alternative	Suzhou Jiahuishu Electronic Co Ltd	2725	Min. 28AWG, Min.30V, Min. 60°C Min. VW-1	UL 758	UL/CSA Recognized (E353532)	
	Alternative	GlobTek, Inc.	2725	Min. 28AWG, Min.30V, Min. 60°C Min. VW-1	UL 758	UL/CSA Recognized (E464257)	
	Alternative	Interchangeable	Interchange able	Min. 28AWG, Min.30V, Min. 60°C Min. VW-1	UL 758	UL/CSA Recognized	



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MET Report: NRTLC128984

## **Critical Drawings**

Title:	Drawing No.:	Rev. Level:	Date:
Transformer construction	Illustration 4		2023-08-15
Circuit diagram	Illustration 5-6	PVT-2	2023-05-01
PCB layout	Illustration 7	REV C	2023-04-14





### Figures

Figure 1.

Over view for GTM961005P-\*PD-USBCP\*\*



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#### Figure 2.

### Over view for GTM961005P-\*PD-USBCJ\*\*







## **Figures (Continued)**

Figure 3.



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#### Figure 4.



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## **Figures (Continued)**

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### Figure 5.



#### Figure 6.



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## **Figures** (Continued)

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Figure 7.

Earthing connection for model GTM961005P-\*PD-USBCP-T3A\*



Figure 8.



Earthing connection for model GTM961005P-\*PD-USBCP-T3\*





## **Figures (Continued)**

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### Figure 9.

### Figure 10.



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## **Figures (Continued)**

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### Figure 11.

Transformer internal view



#### Figure 12.

### Transformer internal view



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## **Figures (Continued)**

### Figure 13.

Transformer internal view

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### Figure 14.

### Transformer internal view







### Figure 15.

### Transformer internal view

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File Number: E115461

### Illustrations

#### **Illustration 1.**



	<sup>®</sup> <b>Inc.</b>	(Families: GT-, GTM, GTH -T2, -T3, -T3A, -T2A, -R2, -R3A)
	NSTALLATION N	MANUAL
INTRODUCTION: Adaptor is a kind of external pieces of electrical equipme moisture proof, and medical	switching power s nt externally. Glob	supply, which is designed to connect Tek's adaptor types include industrial,
INSTALLATION:		
<ol> <li>Before attaching the DC plug the AC power and verify the</li> <li>Keep the linkage between the connecting the DC plug to</li> <li>Protect the power cord from (4) Keep good ventilation for the cm clearance must be kep</li> <li>An approved power cord sin 2/3Gx0.75mm2.</li> <li>If the final equipment is not from power supply to avoid</li> </ol>	of an adaptor to eq unit is within the vol- the adaptor and its equipment properly m being trodden or he unit in use to pre- t when the adjacen hould greater or eq t used for long peri- d being damaged b	uipment, please unplug the adaptor from tage and current rating on the equipment. power cord tightly as well as y. n or being squashed. event it from overheating. Also a 10-15 t device is a heat source. ual to SVT, 2/3Cx18AWG or H05VV-F, iod of time, disconnect the equipment by voltage peaks or lightning strike.
(7) For other information abou	t the products, plea	se refer to www.globtek.com for details.
WARNING/ CAUTION!!		
<ol> <li>Risk of electrical shock and qualified technician. Please</li> <li>Risk of fire or electrical sho objects or dripping liquids.</li> <li>Using wrong DC plug or for device or cause to malfund</li> </ol>	t energy hazard. All do not remove the ock. The openings s roing a DC plug into tion. Please refer t	failure should be examined by a case of the adaptor by yourself! should be protected from foreign o an electronic device may damage the o DC plug compatibility information
(4) Adaptors should be placed	ets. on a reliable surfac	e. A drop or fall could cause damage
(5) Please do not nut adaptors	in places with high	h moisture or near the water.
(6) Please do not put adaptors About the maximum ambie	in places with high nt temperature, plea	ambient temperature or near fire source. ase refer to their specifications.
<ul><li>(7) Output current and output v</li><li>(8) Disconnect the unit from the aerosol cleaner. Only use a</li></ul>	vattage must not ex ne AC power before damp cloth to wip	ceed the rated values on specifications. e cleaning. Do not use any liquid or e it.
(9) Please contact your local q	ualified recyclers w	hen you want to dispose this product.
(10) This appliance is not interphysical, sensory or mental cathey have been given supervision responsible for their sanot play with the appliance.	nded for use by pe apabilities, or lack o sion or instruction o afety. Children shou	rsons (including children) with reduced of experience and knowledge, unless concerning use of the appliance by a uld be supervised to ensure that they do
(11) The appliance inlet is not the appliances IP22, please k	having the same d eep dry before con	legree of protection against moisture as nection.
(12) Please prevent wrapping	the cable around y	our neck to cause asphyxiation





### **Illustrations (Continued)**

#### **Illustration 2.**



Type: ADAPTATEUR	FR
(Families: GT-, GTM, GTH -T2,	

-T3, -T3A, -T2A, -R2, -R3A)

### MANUEL D'INSTALLATION

#### INTRODUCTION:

Un adaptateur est un bloc d'alimentation externe conçu pour relier un équipement électrique au secteur et lui fournir la bonne tension d'alimentation et suffisamment de puissance électrique. Les adaptateurs Globtek incluent des versions dites de bureau ou mural et pouvant répondre à différentes normes comme médicale, ITE, CE ...

#### INSTALLATION:

- Avant de connecter l'adaptateur à votre équipement, veuillez débrancher ce dernier du secteur et vérifier qu'il respecte les valeurs de tension et de courant prescrites pour votre équipement.
- (2) Maintenez bien établie la liaison entre l'adaptateur et son cordon secteur et vérifiez que le connecteur est reliée à l'équipement de manière appropriée.
- (3) Protégez le cordon secteur pour qu'il ne puisse être ni piétiné ni écrasé.

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- (4) Une bonne ventilation de l'adaptateur évitera toute surchauffe durant son utilisation. Respectez également un espace de 10 à 15 cm avec tout appareil produisant de la chaleur.
- (5) Un cordon secteur homologué devra respecter à minima les normes SVT, 2/3Cx18AWG ou H05VV-F, 2/3Gx0.75mm2.
- (6) Si votre équipement n' est pas utilisé pendant une longue période, débranchez-le de l' alimentation pour éviter qu' il ne soit endommagé par des pics de courant ou par la foudre.
- (7) Merci de vous référer au site www.globtek.com pour avoir plus de détails concernant les produits.

#### AVERTISSEMENT/ ATTENTION!!

- (1) Risque de choc électrique ou danger dû à la puissance du courant. Tout dysfonctionnement devra être examiné par un technicien qualifié. Ne retirez pas le boîtier de l' adaptateur vous-même!
- (2) Risque de feu ou de choc électrique. Les ouvertures devront être protégées contre tout objet étranger ou tout liquide ruisselant.
- (3) L'utilisation d'un connecteur inappropriée dans un appareil électronique peut endommager cet appareil ou provoquer un dysfonctionnement. Merci de vous référer aux informations de compatibilité du connecteur dans sa fiche technique.
- (4) Les adaptateurs devront être positionnés sur une surface stable pour que toute chute pouvant provoquer des dégâts puisse être évitée.
- (5) N' installez pas les adaptateurs dans des endroits trop humides ou près d' une source d' eau.
- (6) N' installez pas les adaptateurs dans un endroit soumis à une température ambiante élevée ou près d' une source de feu. Merci de vous référer à leurs spécifications.
- (7) Le courant et la puissance de sortie ne doivent pas excéder les valeurs nominales spécifiées.
- (8) Débranchez l'adaptateur du secteur avant de le nettoyer. N' utilisez aucun nettoyant liquide ou sous forme d'aérosol. Utilisez uniquement un chiffon humide pour l' essuyer.

(9) L'entrée de l'appareil n'a pas le même degré de protection contre l'humidité que l'appareil IP22, veuillez garder au sec avant la connexion.

(10) Veuillez empêcher d'enrouler le câble autour de votre cou pour causer la suffocation.



MET Report: NRTLC128984

### **Illustrations (Continued)**

**Illustration 3.** 



(Serie: GT-, GTM, GTH -T2, -T3, -T3A, -T2A, -R2, -R3A)

### **Operating conditions:**

i. 0°C to 40°C temperature

- ii. Up to 95% relative humidity
- iii. Up to 5000 meters altitude
- iv. 540hPa to 1060hPa

### Storage and transportation conditions:

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i. -40°C to 80°C temperature ii. 0 to 90% humidity iii. 540hPa to 1060hPa

Ta=40°C: IEC 61558-1 Maximum Ambient Temperature, Max 40°C

IP22: Ingress Protection, IP22 to IEC60529:2001 Protection against granular foreign bodies



Attitude up to 5000m



Indoor Use Only



Transformer Symbol IEC 61558-1 SMPS Short-Circuit – Proof Safety Isolating Transformer



Transformer Symbol IEC 61558-1 SMPS Switch Mode Power supply

© 2018-2023 GlobTek, Inc. Manufacturer: GlobTek, Inc, 186 Veterans Drive, Northvale NJ 07647, USA. P/N: 809-DESKTOPUSERMANUAL Rev : A5 The acceptance of this user manual and use of the product described in this document indicates the acceptance and binding of the customer to Globtek terms and conditions, which supersede all other agreements, terms, and conditions (https://en.globtek.com/terms-and-conditions/). The user of this product (Customer) agrees that they are a sophisticated user who understands the technical specifications and safety implications of use of this product described in this specification for their application and to take precautions for protection against any hazards attendant to the handling and use of the product.

MET Report: NRTLC128984

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### **Illustrations (Continued)**

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#### **Illustration 4.**







## **Illustrations (Continued)**

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### **Illustration 5.**







## **Illustrations (Continued)**

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### Illustration 6.







## **Illustrations (Continued)**

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### Illustration 7.







## **Testing Considerations**

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A sample of the power supply with model number GTM961005P-100PD-USBCP-T3A was subjected to the following test program with satisfactory results. All tests were conducted in accordance with: ANSI/ AAMI ES60601-1:2005, ES60601-1:2005/AMD1 1:2012, ES60601-1:2005/AMD2:2021, and CAN/CSA-C22.2 No. 60601-1:14 + A2:22 (R2022), Medical electrical equipment— Part 1: General requirements for basic safety and essential performance

IEC 60601-1-6 Edition 3.2 2020-07 and CAN/CSA-C22.2 NO. 60601-1-6:11 + A1:15 + A2:21 (R2021) Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability;

ANSI/ AAMI HA60601-1-11:2015 [Including AMD1: 2021], CSA C22.2 NO. 60601-1-11:15 (R2020) + A1:21 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

Only these tests were considered necessary due to engineering considerations. Detailed test results are on file at MET Laboratories under project number 128984.

### **TESTS CONDUCTED:**

Item	Clause	Test
1	5.7	Humidity preconditioning treatment
2	5.9.2	Accessible parts
3	7.1.2	Legibility of markings
4	7.1.3	Durability of markings
5	8.7	Leakage currents and patient auxiliary currents
6	8.8.3	Dielectric strength
7	8.9.4	Measurement of creepage distances and air clearances
8	9.4.2.1	Instability in transport position
9	9.4.2.2	Instability excluding transport position
10	11.1.1	Maximum temperature during normal use
11	13.2	Single fault conditions in accordance with 13.2.2 to 13.2.13
12	15.3	Mechanical strength

ANSI AAMI ES60601-1, CSA-C22.2 No. 60601-1

#### ANSI AAMI HA60601-1-11, CSA C22.2 NO. 60601-1-11

Item	Clause	Test
1	4.2.2	Environmental conditions of transport and storage between
		uses
2	4.2.3.1	Continuous operating conditions
3	8.3	Additional requirements for ingress of water or particulate
		matter into me equipment and me systems
4	10.1.2	Requirements for mechanical strength for non-transit-operable
		ME equipment





### Conclusion

The product(s) covered by this report have been tested, examined, and found to comply with the applicable requirements of ANSI/ AAMI ES60601-1:2005, ES60601-1:2005/AMD1 1:2012, ES60601-1:2005/AMD2:2021, and CAN/CSA-C22.2 No. 60601-1:14 + A2:22 (R2022), Medical electrical equipment— Part 1: General requirements for basic safety and essential performance IEC 60601-1-6 Edition 3.2 2020-07 and CAN/CSA-C22.2 NO. 60601-1-6:11 + A1:15 + A2:21 (R2021) Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability; ANSI/ AAMI HA60601-1-11:2015 [Including AMD1: 2021], CSA C22.2 NO. 60601-1-11:15 (R2020) + A1:21 Medical Electrical Equipment -- Part 1-11: General requirements for basic safety and essential performance equipment and medical electrical equipment environment

This certification has been granted under a System 3 program as defined in ISO/IEC Guide 17067.

Prepared By:

Jarle Ca

Jack Gan Project Engineer, Eurofins Electrical Testing Service(Shanghai) Co.,Ltd.

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