

# **RECOGNIZED COMPONENT** **Constructional Data Report (CDR)**

1.0 Reference and Address			
Report Number	130200747SHA-001	Original Issued:	25-Apr-2013
		Revised:	None
Standard(s)	Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance (ANSI/AAMI ES60601-1 Issued: 2006/03/09: 2005 Version (R2012); with AMD C1: 2009, AMD C2: 2010 & CAN/CSA-C22.2 No.60601-1 Issued: 2008/02/01; with COR 2: 2011/06/01)		
Applicant	GlobTek, Inc.	Manufacturer	<b>GlobTek (Suzhou) Co., Ltd.</b>
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2.0 Product Description	
Product	Medical Power Supply
Brand name	GlobTek
Description	<p>Product covered by this report is medical power supply module, which can be used as a part of medical equipment. The different models are corresponding to two structure types respectively. One is power adapter model, which can be used with detachable power supply cord. Different appliance inlets can be interchangeable on the device, which can provide with earthing connection or not. Protective earthing connection to secondary circuit by internal wiring is optional, so it can be Class I or Class II construction. Both two constructions are in consideration in this report. Two pieces of outer enclosure are enclosed with screws. The other one is open frame power supply board which also provides a protective earth bonding terminal on the PCB board. The installation and use for the insulation construction shall be finally determined in the end product.</p> <p>Different transformer types are alternative, which are identical in same construction except different routing of secondary lead wires and shield foil.</p> <p>All the types are designed for continuous operation and no applied part is defined.</p> <p>The insulation construction of EUT is evaluated as 2MOPP in this report.</p>
Models	GT*43004P-***-**(The 1st "*" part can be 'M' or '-' or 'H'; The 2nd "*" part can be "01" to "120", with interval of 1; The 3rd "*" part can be "8.9", "16", "24", "35" or "48"; The 4th "*" part can be "-0.1" to "-12.9" with interval of 0.1 or blank; The 5th "*" part can be 'F' or 'T'; The 6th "*" part can be '2', '3', "3A" or blank.)
Model Similarity	<p>GT*43004P-***-**</p> <p>The 1st "*" part can be 'M' or '-' or 'H' for market identification and not related to safety.</p> <p>The 2nd "*" part denotes the rated output wattage designation, which can be "01" to "120", with interval of 1.</p> <p>The 3rd "*" part denotes the standard rated output voltage designation, which can be "8.9", "16", "24", "35" or "48". Each standard rated output voltage designation corresponds to a transformer model. Each transformer model is identical in insulation construction including clearance and creepage except number of turns per coil.</p> <p>The 4th "*" part is optional, which can be "-0.1" to "-12.9" 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 5-48 volts.</p> <p>The 5th "*" part can be 'F' to denote open frame power supply model or 'T' to denote power adapter model.</p> <p>The 6th "*" part can be '2' to denote Class II model, or '3' or '3A' to denote two types of Class I models with different appliance inlets when the 5th "*" part is 'T'. Otherwise, the 6th "*" part is blank when the 5th "*" part is 'F'.</p>
Ratings	<p>Input: 100-240V~, 50-60Hz, 2.0A;</p> <p>Output: Refer to illustration No.1 for details.</p>
Other Ratings	N/A

## 2.0 Product Description

Conditions of Acceptability	<p>The products covered in this Report are incomplete in construction features or limited in performance capabilities and are intended for use and evaluation in other products. Consideration should be given to the following when the component is used in or with another product.</p> <p>1. Scope of Power Supply evaluation defers the following clauses to be determined as part of the end product investigation:</p> <ul style="list-style-type: none"> <li>• Clause 7.5 (Safety Signs),</li> <li>• Clause 7.9 (Accompanying Documents are provided for some critical issue like technical data, safety warnings, necessary information to set up, but further evaluation is needed on end product level.),</li> <li>• Clause 8.11.5 (Mains Fuse with High Breaking Capacity),</li> <li>• Clause 9 (ME Hazard), except 9.1 and 9.3 are evaluated,</li> <li>• Clause 10 (Radiation),</li> <li>• Clause 11.7 (Biocompatibility),</li> <li>• Clause 14 (PEMS),</li> <li>• Clause 16 (ME Systems)</li> <li>• Clause 17 (EMC),</li> </ul> <p>• Risk Management was excluded from this investigation.</p> <p>• For Power Supplies with No RM: End product Risk Management Process to include consideration of requirements specific to the Power Supply.</p> <p>• For Power Supplies with No RM: End product Risk Management Process to consider the acceptability of risk for the following components that were identified as High-Integrity Component: i.e. Fuse (F1/F2).</p> <p>• For Power Supplies with No RM: End product Risk Management Process to consider the need for simultaneous fault condition testing.</p> <p>• For Power Supplies with No RM: End product Risk Management Process to consider the need for different orientations of installation during testing.</p> <p>• For Power Supplies with No RM and Insulating Materials: End product to determine the acceptability of risk in conjunction to insulation to resistance to heat, moisture, and dielectric strength.</p> <p>• For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the movement of components as part of the power supply.</p> <p>• For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the movement of conductors as part of the power supply.</p> <p>• For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the routing of wires away from moving parts and sharp edges as part of the power supply.</p> <p>• For Power Supplies with No RM or Units without Cleaning/Disinfection Methods: End product to determine the acceptability of risk in conjunction to the Cleaning and Disinfection Methods as part of the power supply.</p> <p>• For Power Supplies with No RM or Units with Enclosures: End product to determine the acceptability of risk in conjunction to the results of Mechanical Testing conducted as part of the power supply.</p> <p>• For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the selection of components as it pertains to the intended use, essential performance, transport, storage conditions as part of the power supply.</p>
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4.0 Critical Components						
Photo #	Item no. <sup>1</sup>	Name	Manufacturer/ trademark <sup>2</sup>	Type / model <sup>2</sup>	Technical data and securement means	Mark(s) of conformity <sup>3</sup>
1	1	Plastic enclosure	SABIC INNOVATIVE PLASTICS B V	SE1X	Min. V-1 at 1.5 mm thickness, 105 °C	cURus
			SABIC INNOVATIVE PLASTICS B V	C2950	Min. V-0 at 1.5 mm thickness, 75° C	
			SABIC INNOVATIVE PLASTICS B V	CX7211 EXCY0098	Min. V-1 at 1.25 mm thickness, 85 °C	
			TEIJIN CHEMICALS LTD	LN-1250P LN-1250G	Min. V-0 at 1.5 mm thickness, 115 °C	
			CHI MEI Corporation	PA-765A	Min. V-1 at 1.5 mm thickness, 80° C	
			CHI MEI Corporation	PC-540	Min. V-0 at 1.5 mm thickness, 70° C	
2	2	Label	DONGGUAN XIANGQUAN PRINTING CO LTD	XQ03	Rated min 80°C Suitable for use on the plastic enclosure	cURus
			FAN JA PAPER PRINTING CO LTD	FJ-03-3		
			FAN JA PAPER PRINTING CO LTD	FJ07		
			DONGGUAN XIANGQUAN PRINTING CO LTD	XQ004-B		
			E-LIN ADHESIVE LABEL CO LTD	EL-15		
			SHENZHEN CORWIN PRINTING CO LTD	CW-01		
			YUEN CHANG SPECIAL PRINTING (SHENZHEN) CO LTD	JL-08 JL-02		
			Various	Various		
			GlobTek	Various	Engraving or Silkscreen (Optional)	NR
3	3	Output cord	Various	Various	Min. 24AWG, min. 300V, min. 80° C	cURus

4.0 Critical Components						
Photo #	Item no. <sup>1</sup>	Name	Manufacturer/ trademark <sup>2</sup>	Type / model <sup>2</sup>	Technical data and securement means	Mark(s) of conformity <sup>3</sup>
3	4	Appliance inlet (only for power adapter model)	Zhejiang LECI Electronics Co., Ltd.	DB-6	2.5A, 250Vac, for Class I model Standard sheet: C6	cURus
			Rich Bay Co., Ltd.	R-30790		
			Sun Fair Electric Wire & Cable (HK)Co. Ltd.	S-02		
			TECX-UNIONS Technology Corporation	TU-333 series		
			Rong Feng Industrial Co., Ltd.	RF-190		
			Inalways Corporation	0724		
			Zhejiang LECI Electronics Co., Ltd.	DB-14	10A, 250Vac, for Class I model Standard sheet: C14	
			Rich Bay Co., Ltd.	R-301SN		
			Sun Fair Electric Wire & Cable (HK)Co. Ltd.	S-03		
			TECX-UNIONS Technology Corporation	TU-301-S TU-301-SP		
			Rong Feng Industrial Co., Ltd.	SS-120		
			Inalways Corporation	0711 series		
			Zhejiang LECI Electronics Co., Ltd.	DB-8	2.5A, 250Vac, for Class II model Standard sheet: C8	
			Rich Bay Co., Ltd.	R-201SN90		
			Sun Fair Electric Wire & Cable (HK)Co. Ltd.	S-01		
			TECX-UNIONS Technology Corporation	SO-222 series		
			Rong Feng Industrial Co., Ltd.	RF-180		
			Inalways Corporation	0721 series		

4.0 Critical Components						
Photo #	Item no. <sup>1</sup>	Name	Manufacturer/ trademark <sup>2</sup>	Type / model <sup>2</sup>	Technical data and securement means	Mark(s) of conformity <sup>3</sup>
4	5	Insulating sheet	FORMEX,DIV OF IL TOOL WORKS INC, FRMRLY FASTEX, DIV OF IL TOOL WORKS INC	FORMEX GK series	V-0, min. 0.4 mm thickness, min. 115°C	cURus
			SKC CO LTD	SH71S	VTM-2, min. 0.4 mm thickness, min. 105°C	
			TORAY INDUSTRIES INC	Lumirror H10	VTM-2, min. 0.4 mm thickness, min. 105°C	
			SABIC INNOVATIVE PLASTICS US L L C	FR60 series FR63 series FR65 series FR7 series FR700 series	V-0, min. 0.4 mm thickness, min. 130°C	
			MIANYANG LONGHUA FILM CO LTD	PP-BK-20 PP-BK-17 PP-BK-18	VTM-0, min. 0.4 mm thickness, min. 80°C	
			ITW ELECTRONICS COMPONENTS/ PRODUCTS (SHANGHAI) CO LTD	FORMEX-18 FORMEX-17	V-0, min. 0.4 mm thickness, min. 100°C	
6	6	Fuse (FS1, FS2)	Conquer Electronics Co., Ltd.	MST	T4A, 250V, Rated breaking capacity 100A	cURus
			Ever Island Electric Co., Ltd. and Walter Electric	2010	T4A, 250V, Rated breaking capacity 130A	
			Bel Fuse Ltd.	RST	T4A, 250V, Rated breaking capacity 100A	
			Cooper Bussmann LLC	SS-5	T4A, 250V, Rated breaking capacity 35A	
			Walter Electronic Co. Ltd.	ICP series	T4A, 250V, Rated breaking capacity 50A	
			Das & Sons International Ltd.	385T series	T4A, 250V, Rated breaking capacity 35A	
			Shenzhen Lanson Electronics Co. Ltd.	SMT	T4A, 250V, Rated breaking capacity 35A	
6	7	Choke coil (LF1) (Optional)	GlobTek BOAM ZhongTong	RC00088	Class A	NR

4.0 Critical Components						
Photo #	Item no. <sup>1</sup>	Name	Manufacturer/ trademark <sup>2</sup>	Type / model <sup>2</sup>	Technical data and securement means	Mark(s) of conformity <sup>3</sup>
6	8	Varistor (MOV1) (optional)	JOYIN CO LTD	07N471K 10N471K 14N471K	Maximum continuous voltage: 300V	cURus
			CENTRA SCIENCE CORP	07D471K 10D471K 14D471K		
			THINKING ELECTRONIC INDUSTRIAL CO LTD	TVR07471K TVR10471K TVR14471K		
			SUCCESS ELECTRONICS CO LTD	SVR07D471K SVR10D471K SVR14D471K		
			CERAMATE TECHNICAL CO LTD	GNR07D471K GNR10D471K GND14D471K		
			BRIGHTKING (SHENZHEN) CO LTD	07D471K 10D471K 14D471K		
			LIEN SHUN ELECTRONICS CO LTD	07D471K 10D471K 14D471K		
			HONGZHI ENTERPRISES LTD	HEL-7D471K HEL-10D471K HEL-14D471K		
			GUANGXI NEW FUTURE INFORMATION INDUSTRY CO LTD	07D471K 10D471K 14D471K		
6	9	Choke coil (LF2) (Optional)	GlobTek ZhongTong BOAM	RC00150	Class A	NR
6	10	Choke coil (L1) (Optional)	GlobTek ZhongTong BOAM	RC00085	Class A	NR
6	11	PFC Choke (L2)	GlobTek BOAM ZhongTong HEJIA	XF00730	Class A	NR

4.0 Critical Components						
Photo #	Item no. <sup>1</sup>	Name	Manufacturer/ trademark <sup>2</sup>	Type / model <sup>2</sup>	Technical data and securement means	Mark(s) of conformity <sup>3</sup>
6	12	X capacitor (CX1) (optional)	Cheng Tung Industrial Co., Ltd.	CTX	Max.0.47uF, 310V, 110°C, type X1 or X2	cURus
			Tenta Electric Industrial Co. Ltd.	MEX	Max.0.47uF, 250V, 110°C, type X2	
			Ultra Tech Xiphi Enterprise Co. Ltd.	HQX	Max.0.47uF, 275V, 100°C, type X2	
			Okaya Electric Industries	RE series	Max.0.47uF, 250V, 110°C, type X2	
			VISHAY Capacitors Belgium NV	F1772	Max.0.47uF, 310V, 110°C, type X1 or X2	
			Winday Electronic Industries Co., Ltd.	MPX	Max.0.47uF, 310V, 110°C, type X2	
			Dain Electronics Co., Ltd.	MPX, MEX and NPX	Max.0.47uF, 250V, 110°C, type X2	
			Sinhua Electronics (Huzhou) Co., Ltd.	MPX	Max.0.47uF, 300V, 110°C, type X2	
			Shunde Da Hua Electric Co., Ltd.	HD-MKP	Max.0.47uF, 250V, 105°C, type X2	
			Foshan Shunde Chuang Ge	MKP-X2	Max.0.47uF, 275V, 105°C, type X2	
			Hongzhi Enterprises Ltd.	MPX	Max.0.47uF, 250V, 100°C, type X2	
			Jiangsu Xinghua Huayu Co., Ltd.	MPX	Max.0.47uF, 250V, 100°C, type X2	
6	13	Insulating tape wrapped around heat-sink	3M COMPANY ELECTRICAL MARKETS DIV (EMD)	1350F series 1350T series 44 series	Min.130°C	cURus
			BONDTEC PACIFIC CO LTD	370S		
			JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CO LTD	PZ series CT series		
			JINGJIANG JINGYI ADHESIVE PRODUCT CO LTD	JY25-A		
			CHANG SHU LIANG YI TAPE INDUSTRY CO LTD	LY-XX		



4.0 Critical Components						
Photo #	Item no. <sup>1</sup>	Name	Manufacturer/ trademark <sup>2</sup>	Type / model <sup>2</sup>	Technical data and securement means	Mark(s) of conformity <sup>3</sup>
6, 13	14	Insulating tube (Used on appliance inlet pin-out or wrapped around heatsink)	SHENZHEN WOER HEAT-SHRINKABLE MATERIAL CO LTD	RSFR RSFR-H RSFR-HPF	600V, 125°C	cURus
			QIFURUI ELECTRONICS CO	QFR-h	600V, 125°C	
			DONGGUAN SALIPT CO LTD	SALIPT S-901-300 SALIPT S-901-600	Min. 300V, 125°C	
			GUANGZHOU KAIHENG ENTERPRISE GROUP	K-2 (+) K-2 (CB)	Min. 300V, 125°C	
			CHANGYUAN ELECTRONICS (SHENZHEN) CO LTD	CB-HFT	Min. 300V, 125°C	
6	15	Y-Capacitor (CY1, CY2) (optional)	TDK-EPC CORPORATION	CD	Type Y1, max. 2200pF, min. 250V, min. 125°C	cURus
			SUCCESS ELECTRONICS CO LTD	SE SB		
			MURATA MFG CO LTD	KX		
			WALSIN TECHNOLOGY CORP	AH		
			JYA-NAY CO LTD	JN		
			HAOHUA ELECTRONIC CO	CT7		
			HONGZHI ENTERPRISES LTD	Y		
			JERRO ELECTRONICS CORP	JX-series		
6, 14-22	16	Transformer (T1)	GlobTek BOAM ZhongTong HEJIA	XF00828 XF00870 XF00849 XF00854 XF00830	Class E,	NR
6, 14-22	16a	Triple-insulated wire (Secondary)	GREAT LEOFLON INDUSTRIAL CO LTD	TRW(B)	Min.130°C	cURus
			COSMOLINK CO LTD	TIW-M		
			FURUKAWA ELECTRIC CO LTD	TEX-E		
			CHANGYUAN ELECTRONICS (SHENZHEN) CO LTD	CB-TIW		
			SHENZHEN JIUDING NEW MATERIAL CO LTD	DTIW-B		

4.0 Critical Components						
Photo #	Item no. <sup>1</sup>	Name	Manufacturer/ trademark <sup>2</sup>	Type / model <sup>2</sup>	Technical data and securement means	Mark(s) of conformity <sup>3</sup>
6, 14-22	16b	Bobbin	CHANG CHUN PLASTICS CO LTD	T375J T375HF	V-0, 150°C, thickness 0.45 mm min.	cURus
			SUMITOMO BAKELITE CO LTD	PM-9820		
			HITACHI CHEMICAL CO LTD	CP-J-8800		
6, 14-22	16c	Insulating tape	3M COMPANY ELECTRICAL MARKETS DIV (EMD)	1350F-1 1350T-1 44	Min.130°C	cURus
			BONDTEC PACIFIC CO LTD	370S		
			JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CO LTD	PZ CT		
			JINGJIANG JINGYI ADHESIVE PRODUCT CO LTD	JY25-A		
			CHANG SHU LIANG YI TAPE INDUSTRY CO LTD	LY-XX		
6	17	Earthing wire for Class I model	KUNSHAN NEW ZHICHENG ELECTRONICS TECHNOLOGIES CO LTD	1015 1007	Min. 20 AWG, Min. 300V, Min. 80° C	cURus
			ZHUANG SHAN CHUAN ELECTRICAL PRODUCTS (KUNSHAN) CO LTD			
			DONGGUAN CHUANTAI WIRE PRODUCTS CO LTD			
			YONG HAO ELECTRICAL INDUSTRY CO LTD			
			DONGGUAN GUNEETAL WIRE & CABLE CO LTD			
			SHENG YU ENTERPRISE CO LTD			
			Various			

4.0 Critical Components						
Photo #	Item no. <sup>1</sup>	Name	Manufacturer/ trademark <sup>2</sup>	Type / model <sup>2</sup>	Technical data and securement means	Mark(s) of conformity <sup>3</sup>
7	18	PCB material	TECHNI TECHNOLOGY LTD	T2A T2B T4	Min 1.6 mm thickness, min. V-0, 130°C	cURus
			DONGGUAN HE TONG ELECTRONICS CO LTD	CEM1		
			CHEERFUL ELECTRONIC	03 03A		
			DONGGUAN DAYSUN ELECTRONIC CO LTD	DS2		
			SUZHOU CITY YILIHUA ELECTRONICS CO LTD	YLH-1		
			SHANGHAI AREX PRECISION ELECTRONIC CO LTD	02V0 04V0		
			BRITE PLUS ELECTRONICS (SUZHOU) CO LTD	DKV0-3A		
			GOLDEN TRIANGLE PCB & TECHNOLOGIES LTD	GT-D		
			SHENZHEN TONGCHUANGXIN ELECTRONICS CO LTD	TCX		
11	19	Optocoupler (U2)	LITE-ON Technology Corporation	LTV-817C	2MOPP at working voltage 250Vrms, 100°C	CB
			Everlight Electronics Co., Ltd.	EL817		

NOTES:

- 1) Not all item numbers are indicated (called out) in the photos, as their location is obvious.
- 2) "Various" means any type, from any manufacturer that complies with the "Technical data and securement means" and meets the "Mark(s) of conformity" can be used.
- 3) Indicates specific marks to be verified, which assures the agreed level of surveillance for the component. "NR" - indicates Unlisted and only visual examination is necessary. "See 5.0" indicates Unlisted components or assemblies to be evaluated periodically refer to section 5.0 for details.

<b>5.0 Critical Unlisted CEC Components</b>
<b>No Unlisted CEC components are used in this report.</b>

## 6.0 Critical Features

Recognized Component - A component part, which has been previously evaluated by an accredited certification body with restrictions and must be evaluated as part of the basic product considering the restrictions as specified by the Conditions of Acceptability.

Listed Component - A component part, which has been previously Listed or Certified by an accredited Certification Organization with no restrictions and is used in the intended application within its ratings.

Unlisted Component - A part that has not been previously evaluated to the appropriate designated component standard. It may also be a Listed or Recognized component that is being used outside of its evaluated Listing or component recognition.

Critical Features/Components - An essential part, material, subassembly, system, software, or accessory of a product that has a direct bearing on the product's conformance to applicable requirements of the product standard.

Construction Details - For specific construction details, reference should be made to the photographs and descriptions. All dimensions are approximate unless specified as exact or within a tolerance. In addition to the specific construction details described in this Report, the following general requirements also apply.

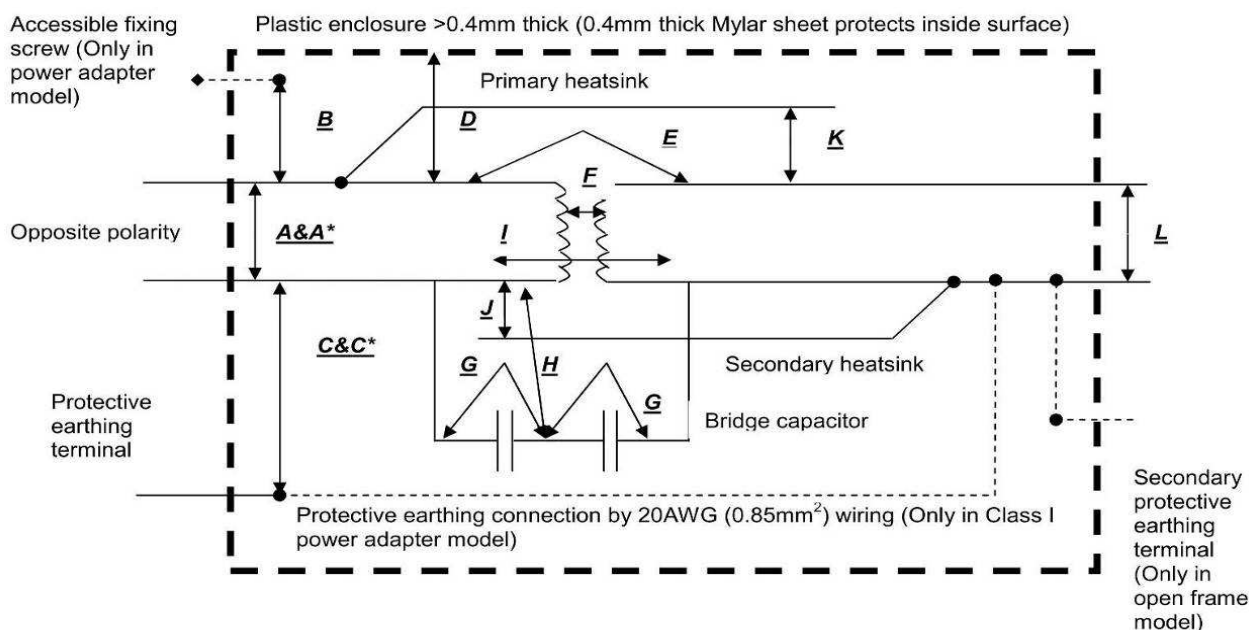
1. Spacing - Refer to illustration No(s) 2-3 for details.
2. Mechanical Assembly - Components such as switches, fuseholders, connectors, wiring terminals and display lamps are mounted and prevented from shifting or rotating by the use of lockwashers, starwashers, or other mounting format that prevents turning of the component.
3. Corrosion Protection - All ferrous metal parts are protected against corrosion by painting, plating or the equivalent.
4. Accessibility of Live Parts - For adapter models, all uninsulated live parts in primary circuitry are housed within a non-metallic enclosure constructed with no openings and metal enclosure earthed with ventilation holes other than those specifically described in Sections 4 and 5.
5. Grounding - This product is not provided with a means of grounding as it is double insulated for Class II model. The accessible contacts of secondary terminal (-) are connected to the equipment grounding terminal for Class I model. Final determination in end product evaluation for open frame model.
6. Polarized Connection - This product is provided with a polarized power supply connection.
7. Internal Wiring - Internal wiring is routed away from sharp or moving parts. Internal wiring leads terminating in soldered connections are made mechanically secure prior to soldering. Recognized Component separable (quick disconnect) connectors of the positive detent type, closed loop connectors, or other types specifically described in the text of this report are also acceptable as internal wiring terminals. At points where internal wiring passes through metal walls or partitions, the wiring insulation is protected against abrasion or damage by plastic bushings or grommets. All wiring is minimum 24 AWG, with a minimum rating of 300V, 80°C.
8. Schematics - Refer to Illustration No(s). 4-5 for schematics & PCB layout requiring verification during Field Representative Inspection Audits.
9. Markings - The product is marked as follows: brand name, model number, electrical ratings, manufacturer. Refer to Illustration No. 6 for details.
10. Cautionary Markings - Refer to illustrations No. 6 for details.
11. Safety Instructions - Accompanying Documents are provided for some critical issue like technical data, safety warnings, necessary information to set up, but further evaluation is needed on end product level.

## 7.0 Illustrations

### Illustration 1 - Model list

Model	Rated output voltage range	Max. rated output current	Max. rated output power	Transformer model
GT*43004P-*8.9*-*	5-8.9Vdc	10A	90W	XF00828
GT*43004P-*16*-*	9-16Vdc	10A	90W	XF00870
GT*43004P-*24*-*	16.1-24Vdc	7.45A	120W	XF00849
GT*43004P-*35*-*	24.1-35Vdc	5A	120W	XF00854
GT*43004P-*48*-*	35.1-48Vdc	3.42A	120W	XF00830

### Illustration 2 - Insulation diagram



### Illustration 3 - TABLE: Insulation diagram (measured values)

TABLE: Insulation diagram (measured values)									P
Pollution degree.....									2
Overvoltage category.....									II
Altitude.....									3000m
Additional details on parts considered as applied parts.....									<input checked="" type="checkbox"/> None <input type="checkbox"/> Areas (See Clause 4.6 for details)
Area	Number and type of Means of Protection: MOOP, MOPP	CTI (IIIb, unless is known)	Working voltage		Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
			Vrms	Vpk					
A	BOP	IIIb	240	--	3	2.1 <sup>7</sup>	4.4 <sup>6</sup>	2.7	Opposite polarity of mains part
A <sup>1</sup>	BOP	IIIb	240	--	3	2.1 <sup>7</sup>	4.3	4.3	Opposite polarity of mains part
B	2MOPP	IIIb	240	--	7.9 <sup>4</sup>	5.0	8.2 <sup>6</sup>	6.6	Accessible metal screws to mains part

## 7.0 Illustrations

Illustration 3 - TABLE: Insulation diagram (measured values) (Cont.)

C	MOPP	IIIb	240	340	4.0	2.5	5.0	5.0	Mains parts to PE terminal (On power inlet)
C <sup>1</sup>	MOPP	IIIb	240	340	4.0	2.5	4.6	4.6	Mains parts to PE terminal (On PCB trace)
D	2MOPP	IIIb	240	340	7.9 <sup>4</sup>	5.0	-- <sup>8</sup>	-- <sup>8</sup>	Internal mains part to accessible outer enclosure (Only for power adapter model)
E	2MOPP	IIIb	240 <sup>3</sup>	--	7.9 <sup>4</sup>	5.0	8.0 <sup>5</sup>	8.0 <sup>5</sup>	Mains parts to secondary pin-out (Optocoupler)
F	2MOPP	IIIb	352 <sup>3</sup>	--	10.7 <sup>4</sup>	7.0	11.5	7.9	Mains parts to secondary pin-out (Transformer)
F <sup>2</sup>	2MOPP	IIIb	240 <sup>3</sup>	--	7.9 <sup>4</sup>	5.0	9.0	9.0	Shield copper foil to secondary pin-out (Transformer)
G	MOPP (Each) x 2	IIIb	240 <sup>3</sup>	--	4.0 <sup>4</sup>	2.5	6.5	6.5	Mains parts to secondary pin-out (Y capacitor x 2)
H	MOPP	IIIb	240 <sup>3</sup>	--	4.0 <sup>4</sup>	2.5	4.6 <sup>6</sup>	2.5	Secondary parts to 1 <sup>st</sup> Y capacitor pin-out (On PCB trace)
I	2MOPP	IIIb	240 <sup>3</sup>	--	7.9 <sup>4</sup>	5.0	8.1	8.1	Mains parts to secondary parts (On PCB trace)
J	2MOPP	IIIb	240 <sup>3</sup>	--	7.9 <sup>4</sup>	5.0	-- <sup>9</sup>	-- <sup>9</sup>	Secondary heatsink to mains parts
K	2MOPP	IIIb	240 <sup>3</sup>	--	7.9 <sup>4</sup>	5.0	8.3	8.3	Primary heatsink to secondary parts
L	2MOPP	IIIb	Max. 48Vdc	--	--	--	--	--	Accessible parts per 8.4.2 c)

**Note:**

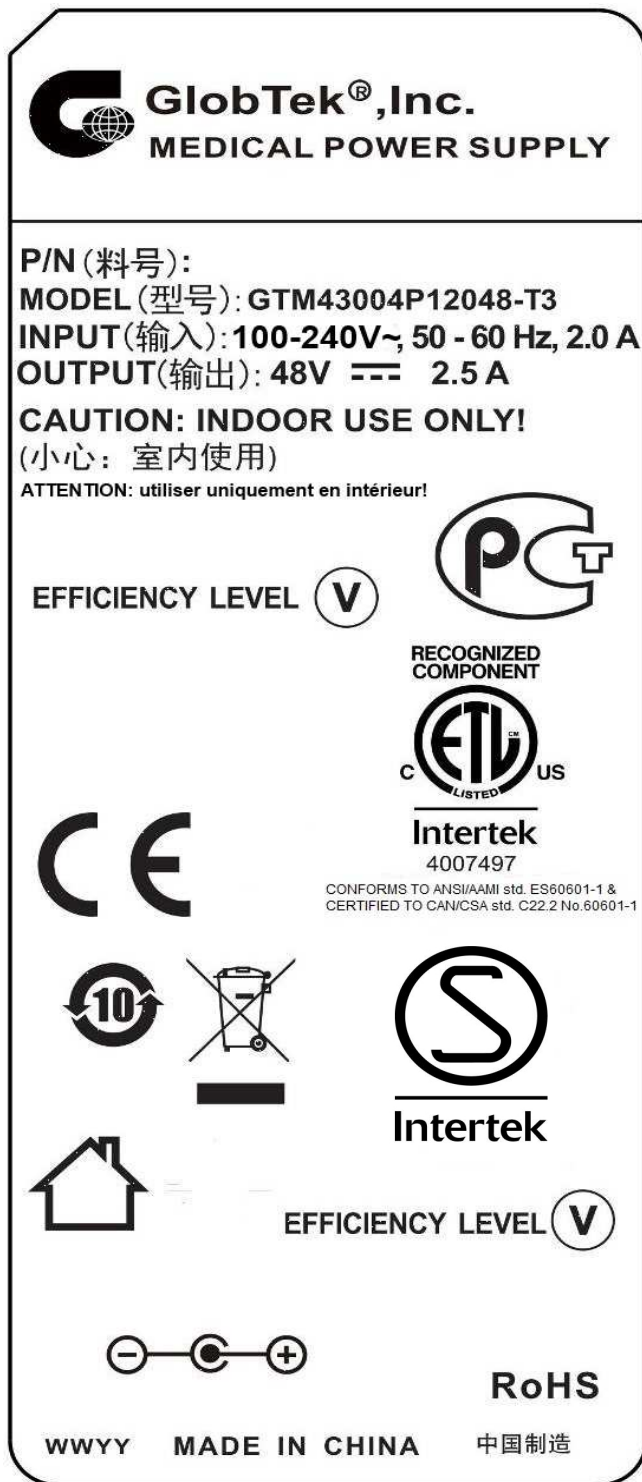
- 1) The same area is evaluated in open frame model. And there is no more difference if not specified.
- 2) Optionally an electromagnetic shield which is copper foil is added around the outside of the coil. It's connected to mains part.
- 3) The working voltage is highest measured value which acquired by testing all the models listed in the report at the rated input voltage, but not less than the rated input voltage.
- 4) Linear interpolation is applied to the determination of required creepage.
- 5) The minimum creepage and clearance is selected from all the types of optocouplers.
- 6) There is a slot min. 1 mm wide between these two parts.
- 7) Multiplication factor for MOOP: 1.14; Multiplication factor for MOPP: 1.00.
- 8) Minimum 0.4 mm thick Mylar sheet wraps around internal conductive parts.
- 9) Two layers of insulating tape or one layer of min. 0.4 mm thickness insulating tube wrap around the secondary heatsink.

## 7.0 Illustrations

### Illustration 6 - Marking label

The marking plates of the other models listed in this report are identical with below except model name and output parameter.

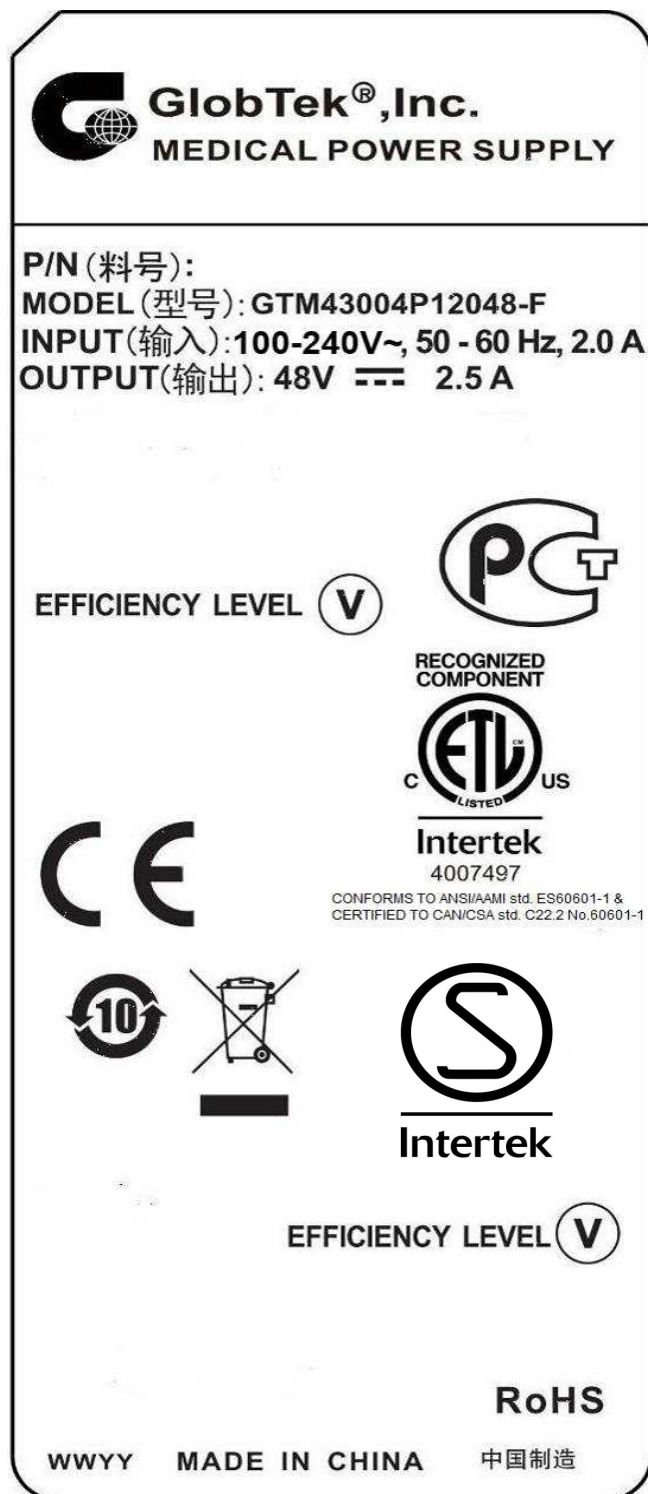
For power adapter model, the left one represents Class I model series & the right one represents Class II model series.



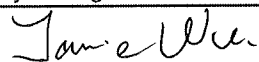
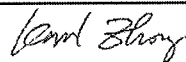


## 7.0 Illustrations

Illustration 6 - Marking label (Cont.)  
For open frame model



8.0 Test Summary			
Evaluation Period	2013-02-25 ~ 2013-04-24		Project No. 130200747SHA
Sample Rec. Date	25-Feb-2013	Condition	Prototype
			Sample ID. 0130225-17-001
Test Location	Building No.86, 1198 Qinzhou Road (North), Shanghai 200233, China		
Test Procedure	Testing Lab		
Determination of the result includes consideration of measurement uncertainty from the test equipment and methods. The product was tested as indicated below with results in conformance to the relevant test criteria.			
The following tests were performed:			
Test Description	Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance (ANSI/AAMI ES60601-1 Issued: 2006/03/09: 2005 Version (R2012); with AMD C1: 2009, AMD C2: 2010 & CAN/CSA-C22.2 No.60601-1 Issued: 2008/02/01; with COR 2: 2011/06/01)		
	Clause		
Power Input	4.11		
Humidity Preconditioning	5.7		
Accessible Parts	5.9.2		
Legibility of Markings	7.1.2		
Durability of Markings	7.1.3		
Plug Voltage and/or Energy	8.4.3		
Working Voltage Measurement	8.5.4		
Earthing	8.6.4		
Leakage Current Test terminations	8.7.4		
Dielectric Strength Means	8.8.3		
Ball Pressure Test	8.8.4.1		
Creepage & Clearance Measurements	8.9.4		
Excessive Temperature	11.1		
Single Fault Conditions	13.2		
Push Test	15.3.2		
Impact Test	15.3.3		
Drop Test	15.3.4		
Moulding Stress Relief	15.3.6		
Transformer Short-Circuit	15.5.1.2		
Transformer Overload	15.5.1.3		
Transformer Dielectric Strength	15.5.2		

8.1 Signatures			
A representative sample of the product covered by this report has been evaluated and found to comply with the applicable requirements of the standards indicated in Section 1.0.			
Completed by:	Jamie Wu	Reviewed by:	Karl Zhong
Title:	Project engineer	Title:	Reviewer
Signature:		Signature:	

## 9.0 Correlation Page For Multiple Listings

The following products, which are identical to those identified in this report except for model number and Listee name, are authorized to bear the ETL label under provisions of the Intertek Multiple Listing Program.

BASIC LISTEE	GlobTek, Inc.
Address	186 Veterans Dr. Northvale, NJ 07647 USA
Country	USA
Product	Medical Power Supply

MULTIPLE LISTEE 1	None
Address	
Country	
Brand Name	
ASSOCIATED MANUFACTURER	
Address	
Country	
MULTIPLE LISTEE 1 MODELS	BASIC LISTEE MODELS

MULTIPLE LISTEE 2	None
Address	
Country	
Brand Name	
ASSOCIATED MANUFACTURER	
Address	
Country	
MULTIPLE LISTEE 2 MODELS	BASIC LISTEE MODELS

MULTIPLE LISTEE 3	None
Address	
Country	
Brand Name	
ASSOCIATED MANUFACTURER	
Address	
Country	
MULTIPLE LISTEE 3 MODELS	BASIC LISTEE MODELS

## 10.0 General Information

The Applicant and Manufacturer have agreed to produce, test and label ETL Listed products in accordance with the requirements of this Report. The Manufacturer has also agreed to notify Intertek and to request authorization prior to using alternate parts, components or materials.

### COMPONENTS

Components used shall be those itemized in this Intertek report covering the product, including any amendments

### LISTING MARK

The ETL Listing mark applied to the products shall either be separable in form, such as labels purchased from Intertek, or on a product nameplate or other media only as specifically authorized by Intertek. Use of the mark is subject to the control of Intertek.

The mark must include the following four items:

- 1) applicable country identifiers "US" and/or "C" or "US", "C" and "EU"
- 2) the word "Listed" or "Classified" or "Recognized Component" (whichever is appropriate)
- 3) a control number issued by Intertek
- 4) a product descriptor that identifies the standards used for certification. Example:

**For US standards**, the words, "Conforms to" shall appear with the standard number along with the word, "Standard" or "Std." Example: "Conforms to ANSI/UL Std. XX."

**For Canadian standards**, the words "Certified to CAN/CSA Standard CXX No. XX." shall be used, or abbreviated, "Cert. to CAN/CSA Std. CXX No. XX."

Can be used together when both standards are used.

**Note: A facsimile must be submitted to Intertek, Attn: Follow-up Services for approval prior to use.**

The facsimile need not have a control number. A control number will be issued **after signed Certification Agreements** have been received by the Follow-up Services office, approval of the facsimile of your proposed Listing Mark, satisfactory completion of the Listing Report, and scheduling of a factory assessment in your facility.

### MANUFACTURING AND PRODUCTION TESTS

Manufacturing and Production Tests shall be performed as required in this Report.

### FOLLOW-UP SERVICE

Periodic unannounced audits of the manufacturing facility (and any locations authorized to apply the mark) shall be scheduled by Intertek. An audit report shall be issued after each visit. Special attention will be given to the following:

1. Conformance of the manufactured product to the descriptions in this Report.
2. Conformance of the use of the ETL mark with the requirements of this Report and the Certification Agreement.
3. Manufacturing changes.
4. Performance of specified Manufacturing and Production Tests.

In the event that the Intertek representative identifies non-conformance(s) to any provision of this Report, the Applicant shall take one or more of the following actions:

1. Correct the non-conformance.
2. Remove the ETL Mark from non-conforming product.
3. Contact the issuing product safety evaluation center for instructions.

### 10.1 Evaluation of Unlisted Components

Because Unlisted Components are uncontrolled, and they do not fall under a third party follow up program, Intertek may require these components to be tested and/or evaluated at least once annually, more often for certain components, as part of the independent certification process. The Unlisted Components in Section 5.0 require testing and/or evaluation as indicated.

**Note to Intertek Follow Up Inspector: The Component Evaluation Center, CEC, will notify you in writing when these components must be selected and sent to the CEC for re-evaluation**

Ship the samples to:  
Intertek Testing Services Shanghai Limited  
ETL Component Evaluation Center  
Building No. 86, 1198 Qinzhou Road (North)  
Shanghai 200233, China  
Attn: Ms. Dansy Xu

Sample Disposition: Due to the destructive nature of the testing, all samples will be discarded at the conclusion of testing unless, the manufacturer specifically requests the return of the samples. The request for return must accompany the initial component shipment.

## 11.0 Manufacturing and Production Tests

The manufacturer agrees to conduct the following Manufacturing and Production Tests as specified:

### Required Tests

Dielectric Voltage Withstand Test  
Grounding Continuity Test

## 11.1 Dielectric Voltage Withstand Test

### Method

One hundred percent of production of the products covered by this Report shall be subjected to a routine  
The test shall be conducted on products, which are fully assembled. Prior to applying the test potential, all  
The test voltage specified below shall be applied between primary circuits and accessible dead-metal parts. The

### Test Equipment

The test equipment shall incorporate a transformer with an essentially sinusoidal output, a means to indicate the  
The test equipment shall incorporate a voltmeter in the output circuit to indicate directly the applied test potential  
If the rated output of the test equipment is 500VA or more, the applied test potential may be indicated by either:

### **Products Requiring Dielectric Voltage Withstand Test:**

<u>Product</u>	<u>Test Voltage</u>	<u>Test Time</u>
Between mains part and secondary circuits for Class II model and open frame model	4000Vac	1 s
Between mains part and secondary circuits (earthing) for Class I model only	1500Vac	1 s

## 11.2 Grounding Continuity Test

### Method

Each product listed below shall be subjected to a test to determine that there is continuity between accessible  
contacts of secondary terminal of the product and the grounding pin of the appliance inlet.

If accessible contacts of secondary terminal (-) are connected, only a single test need be performed. A visual or  
audible device (ohmmeter, buzzer, etc.) may be used to indicate grounding continuity.

### **Products Requiring Grounding Continuity Test:**

Class I model covered by this Report.

The following changes are in compliance with the declaration of Section 8.1:

[illegible]