
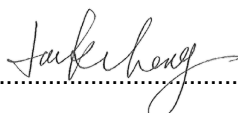


<b>VERIFICATION STATEMENT</b> <b>EN 60601-1:2006/ A1:2013+A12:2014</b> <b>Part 1: General requirements for basic safety and essential performance</b>	
<b>Report Reference No.</b> .....	200200842SHA-001 (based on CB certif. no. SE-85947)
<b>Tested by (+ signature)</b> .....	Yann Yan 
<b>Approved by (+ signature)</b> .....	Jack Cheng 
<b>Date of issue</b> .....	2020.02.26
<b>Contents</b> .....	11 pages
<b>Testing laboratory Name</b> .....	Intertek Testing Services Shanghai
<b>Address</b> .....	Building 86, 1198 Qinzhou Road (North), 200233 Shanghai, China
<b>Testing location</b> .....	Same as above
<b>Client Name</b> .....	GlobTek, Inc.
<b>Address</b> .....	186 Veterans Dr. Northvale, NJ 07647 USA
<b>Standard</b> .....	EN 60601-1:2006/ A1:2013+A12:2014
<b>Test procedure</b> .....	S mark
<b>Non-standard test method</b> .....	N.A.
<b>Test item Description</b> .....	Medical Power supply
<b>Trademark</b> .....	GlobTek
<b>Model and/or type reference</b> .....	GT*41080*****
<b>Rating(s)</b> .....	Input: 100-240V~, 50-60Hz, 0.6A; Output: 5-48V, Max.3.6A, Max 18W
<b>Manufacture</b> .....	GlobTek, Inc. 186 Veterans Dr. Northvale, NJ 07647 USA
<b>Factory</b> .....	1. GlobTek, Inc. 186 Veterans Dr. Northvale, NJ 07647 USA 2. GlobTek (Suzhou) Co., Ltd Building 4, No. 76 JinLing East Road, Suzhou Industrial Park, Suzhou, JiangSu, 215021, China
<b>Remarks for acceptance and review work conducted by above qualified testing laboratory</b>	
<b>Sample Number reviewed</b> .....	1 pcs

Remark .....	: The product and the mentioned test reports comply with Swedish standard and national's deviations, if any. The sample as shown in following page(s) is still corresponding with the one mentioned in CB test report. We concluded this statement verifies that above standards are fulfilled.
Test item description .....	: No tests are needed for this product.
Statement for deviations, if any.....	: National difference for Sweden has been evaluated in CB report.

**Specification and key information involved in original CB certificate and test report**

Involved Ref. Certif. no .....	SE-85947
Issued date.....	2017-02-09
Test item description.....	Medical Power supply
Applicant's Name .....	GlobTek, Inc.
Address .....	186 Veterans Dr. Northvale, NJ 07647 USA
Manufacturer .....	GlobTek, Inc. 186 Veterans Dr. Northvale, NJ 07647 USA
Factory .....	1. GlobTek, Inc. 186 Veterans Dr. Northvale, NJ 07647 USA 2. GlobTek (Suzhou) Co., Ltd Building 4, No. 76 JinLing East Road, Suzhou Industrial Park, Suzhou, JiangSu, 215021, China
Technical data.....	Input: 100-240V~, 50-60Hz, 0.6A; Output: 5-48V, Max.3.6A, Max 18W
Referred standard .....	The product fulfils the requirements of IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 & EN 60601-1:2006 + A11:2011 + A1:2013 & ANSI/AAMI ES60601-1:2005/A1:2012 & CAN/CSA-C22.2 No. 60601-1:14.
Model and/or type reference .....	GT*41080*****
Involved test report .....	161100155SHA-001

**GT\*41080\*\*\*\*\***

The 1st “\*” part can be ‘M’ or ‘-’ or ‘H’ for market identification and not related to safety.

The 2nd “\*” part can be “-” or “CC”, “-” = Constant Voltage Model, CC = Constant Current Model.

The 3rd “\*” part denotes the rated output wattage designation, which can be “01” to “18”, with interval of 1.

The 4rd “\*” part denotes the standard rated output voltage designation, which can be “07”, “11” “17.9”, “30”, “38” and “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.

The 5th “\*” part is optional, which can be “-0.1” to “-12.0” 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 - 48 volts.

The 6th “\*” part is also optional, which can be “-F” to denote open frame power supply model series or blank to denote direct plug-in power adapter model series.

8.10	TABLE: List of critical components					P
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./, Edition	Mark(s) & Certificates of conformity <sup>1)</sup>	
PCB	WALEX ELECTRONIC (WUXI)CO LTD	T2 T2A T2B T4	Min 1.6 mm thickness, min. V-0, 130°C	IEC 60601-1 UL 796	UL E154355	
Alt.	DONGGUAN HE TONG ELECTRONICS CO LTD	CEM1	Min 1.6 mm thickness, min. V-0, 130°C	IEC 60601-1 UL 796	UL E243157	
Alt.	CHEERFUL ELECTRONIC	02 03 03A	Min 1.6 mm thickness, min. V-0, 130°C	IEC 60601-1 UL 796	UL E199724	
Alt.	DONGGUAN DAYSUN ELECTRONIC CO LTD	DS2	Min 1.6 mm thickness, min. V-0, 130°C	IEC 60601-1 UL 796	UL E251754	
Alt.	SUZHOU CITY YILIHUA ELECTRONICS CO LTD	YLH-1, YLH-2	Min 1.6 mm thickness, min. V-0, 130°C	IEC 60601-1 UL 796	UL E251781	
Alt.	SHANGHAI AREX PRECISION ELECTRONIC CO LTD	02V0, 04V0	Min 1.6 mm thickness, min. V-0, 130°C	IEC 60601-1 UL 796	UL E186016	
Alt.	BRITE PLUS ELECTRONICS (SUZHOU) CO LTD	DKV0-3A DGV0-3A	Min 1.6 mm thickness, min. V-0, 130°C	IEC 60601-1 UL 796	UL E177671	
Alt.	SHENZHEN TONGCHUANGX IN ELECTRONICS CO LTD	TCX	Min 1.6 mm thickness, min. V-0, 130°C	IEC 60601-1 UL 796	UL E177671	
Alt.	PACIFIC WIN INDUSTRIAL LTD	PW-02 PW-03	Min 1.6 mm thickness, min. V-0, 130°C	IEC 60601-1 UL 796	UL E177671	
Alt.	Interchangeable	Interchangeable	Min 1.6 mm thickness, min. V-0, 130°C	IEC 60601-1 UL 796	UL E177671	
Fuse (FS1, FS2)	Conquer Electronics Co., Ltd.	MST	T1.6A, 250V, Rated breaking capacity 100A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40017118 UL E82636	
Alt.	Ever Island Electric Co., Ltd. and Walter Electric	2010	T1.6A, 250V, Rated breaking capacity 130A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40018781 UL E220181	

Alt.	Bel Fuse Ltd.	RST	T1.6A, 250V, Rated breaking capacity 100A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40011144 UL E20624
Alt.	Cooper Bussmann LLC	SS-5	T1.6A, 250V, Rated breaking capacity 35A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40015513 UL E19180
Alt.	Walter Electronic Co. Ltd.	ICP series	T1.6A, 250V, Rated breaking capacity 50A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40012824 UL E56092
Alt.	Das & Sons International Ltd.	385T series	T1.6A, 250V, Rated breaking capacity 35A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40008524 UL E205718
Alt.	Shenzhen Lanson Electronics Co. Ltd.	SMT T1,6A250V	T1.6A, 250V, Rated breaking capacity 35A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40012592 UL E221465
Alt.	Sun Electric Co.	5H	T1.6A, 250V, Rated breaking capacity 35A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40012592 UL E221465
X capacitor (CX1) (optional)	Cheng Tung Industrial Co., Ltd.	CTX	Max.0.22uF, 310V, 110°C, type X1 or X2	IEC/EN 60384- 14 UL 1414	VDE 40022642 UL E193049
Alt.	Tenta Electric Industrial Co. Ltd.	MEX	Max.0.22uF, 250V, 110°C, type X2	IEC/EN 60384- 14 UL 60384-14 UL 1414	VDE 119119 UL E222911
Alt.	Ultra Tech Xiphi Enterprise Co. Ltd.	HQX	Max.0.22uF, 275V, 100°C, type X2	IEC/EN 60384- 14 UL 60384-14 UL 1414	VDE 40022642 UL E183780
Alt.	Okaya Electric Industries	RE series	Max.0.22uF, 250V, 110°C, type X2	IEC/EN 60384- 14 UL 60384-14 UL 1414	VDE 40028657 UL E47474
Alt.	VISHAY Capacitors Belgium NV	F1772	Max.0.22uF, 310V, 110°C, type X1 or X2	IEC/EN 60384- 14 UL 60384-14 UL 1414	VDE 40005079 UL E354331
Alt.	Winday Electronic Industries Co., Ltd.	MPX	Max.0.22uF, 310V, 110°C, type X2	IEC/EN 60384- 14 UL 60384-14 UL 1414	VDE 40018071 UL E302125

Alt.	Dain Electronics Co., Ltd.	MPX, MEX and NPX	Max.0.22uF, 250V, 110°C, type X2	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40018798 UL E147776
Alt.	Sinhua Electronics (Huzhou) Co., Ltd.	MPX	Max.0.22uF, 300V, 110°C, type X2	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40014686 UL E237560
Alt.	Shunde Da Hua Electric Co., Ltd.	HD-MKP	Max.0.22uF, 250V, 105°C, type X2	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40001126 UL E227157
Alt.	Foshan Shunde Chuang Ge	MKP-X2	Max.0.22uF, 275V, 105°C, type X2	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40008922 UL E308832
Alt.	Hongzhi Enterprises Ltd.	MPX	Max.0.22uF, 250V, 100°C, type X2	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40023936 UL E192572
Alt.	Jiangsu Xinghua Huayu Co., Ltd.	MPX	Max.0.22uF, 250V, 100°C, type X2	IEC/EN 60384-14	VDE 40022417
Y-Capacitor (CY1, CY2) (optional)	TDK-EPC CORPORATION	CD	Type Y1, max. 2200pF, min. 250V, min. 125°C	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 138526 UL E37861
Alt.	SUCCESS ELECTRONICS CO LTD	SE SB	Type Y1, max. 2200pF, min. 250V, min. 125°C	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40008996 UL E114280
Alt.	MURATA MFG CO LTD	KX	Type Y1, max. 2200pF, min. 250V, min. 125°C	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40002831 UL E37921
Alt.	WALSIN TECHNOLOGY CORP	AH	Type Y1, max. 2200pF, min. 250V, min. 125°C	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40001804 UL E146544
Alt.	JYA-NAY CO LTD	JN	Type Y1, max. 2200pF, min. 250V min. 125°C	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40001831 UL E201384

Alt.	HAOHUA ELECTRONIC CO	CT7	Type Y1, max. 2200pF, min. 250V, min. 125°C	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40003902 UL E233106
Alt.	HONGZHI ENTERPRISES LTD	Y	Type Y1, max. 2200pF, min. 250V, min. 125°C	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40004354 UL E192572
Alt.	JERRO ELECTRONICS CORP	JX-series	Type Y1, max. 2200pF, min. 250V, min. 125°C	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40032158 UL E333001
Varistor (MOV1) (optional)	JOYIN CO LTD	07N471K 10N471K 14N471K	300Vac	IEC 61051-2 UL 1449	VDE 005937 UL E325508
Alt.	CENTRA SCIENCE CORP	07D471K 10D471K 14D471K	300Vac	IEC 61051-2 UL 1449	VDE 40008220 UL E316325
Alt.	THINKING ELECTRONIC INDUSTRIAL CO LTD	TVR07471K TVR10471K TVR14471K	300Vac	IEC 61051-2 UL 1449	VDE 005944 UL E314979
Alt.	SUCCESS ELECTRONICS CO LTD	SVR07D471K SVR10D471K SVR14D471K	300Vac	IEC 61051-2 UL 1449	VDE 40030401 UL E330256
Alt.	CERAMATE TECHNICAL CO LTD	GNR07D471K GNR10D471K GND14D471K	300Vac	IEC 61051-2 UL 1449	VDE 40031745 UL E315429
Alt.	BRIGHTKING (SHENZHEN) CO LTD	07D471K 10D471K 14D471K	300Vac	IEC 61051-2 UL 1449	VDE 40027827 UL E327997
Alt.	LIEN SHUN ELECTRONICS CO LTD	07D471K 10D471K 14D471K	300Vac	IEC 61051-2 UL 1449	VDE 40005858 UL E315524
Alt.	HONGZHI ENTERPRISES LTD	HEL-7D471K HEL-10D471K HEL-14D471K	300Vac	IEC 61051-2 UL 1449	VDE 40008621 UL E324904
Alt.	GUANGXI NEW FUTURE INFORMATION INDUSTRY CO LTD	07D471K 10D471K 14D471K	300Vac	IEC 61051-2 UL 1449	VDE 40030322 UL E323753

Optocoupler (U1)	LITE-ON Technology Corporation	LTV-817C	2MOPP at working voltage 250Vrms, 100°C	IEC 60601-1:2005 + CORR.1:2006 + CORR.2:2007	SIQ CB Report No.T223-0437/12
Alt.	Everlight Electronics Co., Ltd.	EL817	2MOPP at working voltage 250Vrms, 100°C	IEC 60601-1:2005 + CORR.1:2006 + CORR.2:2007	SIQ CB Report No.T223-0106/13
Transformer (T1)	ENG GlobTek BOAM HAOPUWEI HEJIA	XF00514 XF00550 XF00579 XF00590 XF00682A XF00682	Class E, with critical component listed below	IEC 60601-1:2005 + CORR.1:2006 + CORR.2:2007	Tested with appliance
-Triple-insulated wire (Secondary)	GREAT LEOFLON INDUSTRIAL CO LTD	TRW(B)	Min.130°C	IEC 60950-1 UL 2353 UL 60601-1	UL E211989
-Alt.	COSMOLINK CO LTD	TIW-M	Min.130°C	IEC 60950-1 UL 2353 UL 60601-1	UL E213764
-Alt.	FURUKAWA ELECTRIC CO LTD	TEX-E	Min.130°C	IEC 60950-1 UL 2353 UL 60601-1	UL E206440
-Bobbin	CHANG CHUN PLASTICS CO LTD	T375J T375HF	V-0, 150°C, thickness 0.45 mm min.	IEC 60950-1 UL 94 UL 746 A/B/C/D	UL E59481
-Alt.	SUMITOMO BAKELITE CO LTD	PM-9820	V-0, 150°C, thickness 0.45 mm min.	IEC 60950-1 UL 94 UL 746 A/B/C/D	UL E41429
-Alt.	HITACHI CHEMICAL CO LTD	CP-J-8800	V-0, 150°C, thickness 0.45 mm min.	IEC 60950-1 UL 94 UL 746 A/B/C/D	UL E42956
-Insulating tape	3M COMPANY ELECTRICAL MARKETS DIV (EMD)	1350F-1 1350T-1	Min.130°C	IEC 60950-1 UL 510	UL E17385
-Alt.	BONDTEC PACIFIC CO LTD	370S	Min.130°C	IEC 60950-1 UL 510	UL E175868
-Alt.	JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CO LTD	PZ CT	Min.130°C	IEC 60950-1 UL 510	UL E165111



-Alt.	JINGJIANG JINGYI ADHESIVE PRODUCT CO LTD	JY25-A	Min.130°C	IEC 60950-1 UL 510	UL E246950
-Alt.	CHANG SHU LIANG YI TAPE INDUSTRY CO LTD	LY-XX	Min.130°C	IEC 60950-1 UL 510	UL E246820
Line filter (LF1)	ENG GlobTek BOAM HAOPUWEI HEJIA	NF00001D	Class A	IEC 60601- 1:2005 + CORR.1:2006 + CORR.2:2007	Tested with appliance
Enclosure and Blade holder	SABIC INNOVATIVE PLASTICS B V	SE1X SE1 SE100	Min. V-1 at 1.5 mm thickness, 105°C	IEC 60950-1 UL 94 UL 746 A/B/C/D	UL E45329
Alt.	SABIC INNOVATIVE PLASTICS B V	C2950	Min. V-0 at 1.5 mm thickness, 75°C	IEC 60950-1 UL 94 UL 746 A/B/C/D	UL E45329
Alt.	SABIC INNOVATIVE PLASTICS B V	CX7211 EXCY0098	Min. V-1 at 1.25 mm thickness, 85°C	IEC 60950-1 UL 94 UL 746 A/B/C/D	UL E45329
Alt.	TEIJIN CHEMICALS LTD	LN-1250P LN-1250G	Min. V-0 at 1.5 mm thickness, 115°C	IEC 60950-1 UL 94 UL 746 A/B/C/D	UL E50075
Alt.	CHI MEI Corporation	PA-765A	Min. V-1 at 1.5 mm thickness, 80°C	IEC 60950-1 UL 94 UL 746 A/B/C/D	UL E56070
Alt.	CHI MEI Corporation	PC-540	Min. V-0 at 1.5 mm thickness, 70°C	IEC 60950-1 UL 94 UL 746 A/B/C/D	UL E56070
Blade holder	SABIC INNOVATIVE PLASTICS B V	SE1X	Min. V-1 at 1.5 mm thickness, 105°C	IEC 60950-1 UL 94 UL 746 A/B/C/D	UL E45329
Alt.	SABIC INNOVATIVE PLASTICS B V	C2950	Min. V-0 at 1.5 mm thickness, 75°C	IEC 60950-1 UL 94 UL 746 A/B/C/D	UL E45329
Alt.	SABIC INNOVATIVE PLASTICS B V	CX7211 EXCY0098	Min. V-1 at 1.25 mm thickness, 85°C	IEC 60950-1 UL 94 UL 746 A/B/C/D	UL E45329

Alt.	TEIJIN CHEMICALS LTD	LN-1250P LN-1250G	Min. V-0 at 1.5 mm thickness, 115°C	IEC 60950-1 UL 94 UL 746 A/B/C/D	UL E50075
Alt.	CHI MEI Corporation	PA-765A	Min. V-1 at 1.5 mm thickness, 80°C	IEC 60950-1 UL 94 UL 746 A/B/C/D	UL E56070
Alt.	CHI MEI Corporation	PC-540	Min. V-0 at 1.5 mm thickness, 70°C	IEC 60950-1 UL 94 UL 746 A/B/C/D	UL E56070
Output cord	Interchangeable	Interchangeable	Min. 24AWG, min. 300V, min. 80°C	IEC/EN 60950-1 UL 758	Tested with appliance UL approved
Label	DONGGUAN XIANGQUAN PRINTING CO LTD	Type XQ03	Rated min 80°C Suitable for use on the plastic enclosure	IEC/EN 60601-1 UL 969	UL MH27594
Alt.	FAN JA PAPER PRINTING CO LTD	Type FJ-03-3	Rated min 80°C Suitable for use on the plastic enclosure	IEC/EN 60601-1 UL 969	UL MH19546
Alt.	FAN JA PAPER PRINTING CO LTD	Type FJ07	Rated min 80°C Suitable for use on the plastic enclosure (PC or ABS)	IEC/EN 60601-1 UL 969	UL MH19546
Alt.	DONGGUAN XIANGQUAN PRINTING CO LTD	Type XQ004-B	Rated min 80°C Suitable for use on the plastic enclosure	IEC/EN 60601-1 UL 969	UL MH47303
Alt.	E-LIN ADHESIVE LABEL CO LTD	Type EL-15	Rated min 80°C Suitable for use on the plastic enclosure	IEC/EN 60601-1 UL 969	UL MH45549
Alt.	SHENZHEN CORWIN PRINTING CO LTD	CW-01	Rated min 80°C Suitable for use on the plastic enclosure	IEC/EN 60601-1 UL 969	UL MH47077
Alt.	YUEN CHANG SPECIAL PRINTING (SHENZHEN) CO LTD	JL-08	Rated min 80°C Suitable for use on the plastic enclosure (PC or ABS)	IEC/EN 60601-1 UL 969	UL MH29752
Alt.	GlobTek	---	Engraving Silkscreen Laser printing	IEC/EN 60601-1	Tested with appliance

<b>Switch</b> (Output cord) (optional)	OPENWISE INDUSTRIAL LTD	<b>303</b>	Through-cord single-pole, rated 2A 250V	EN 61058-1 EN 61058-2-1 UL 20	VDE: 106396 UL E213260
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**Supplementary information:**

1) Indicates a mark which assures the agreed level of surveillance. See Licenses and Certificates of Conformity for verification.