VERIFICATION STATEMENT

EN 60601-1-11:2015

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

Report Reference No. ..... :	170500751SHA-002 (based on CB certif. no. SE-87772)
Tested by (+ signature) ..... :	Fitzgerald Zhang
Approved by (+ signature)..... :	Justin Yu
Date of issue ..... :	2017-07-28
Contents ..... :	8 pages
Testing laboratory Name..... :	Intertek Testing Services Shanghai
Address ..... :	Building 86, 1198 Qinzhou Road (North), 200233 Shanghai, China
Testing location ..... :	Same as above
Client Name..... :	GlobTek, Inc.
Address ..... :	186 Veterans Dr. Northvale, NJ 07647 USA
Standard..... :	EN 60601-1-11:2015
Test procedure ..... :	S mark
Non-standard test method ..... :	N.A.
Test item Description ..... :	Medical Power supply
Trademark..... :	GlobTek, Inc.
Model and/or type reference ..... :	GT*46161-**-USB
Rating(s)..... :	Input: 100-240V~, 50-60Hz, 0.45A Output: 5.0-5.5Vdc, Max.16W
Manufacture ..... :	GlobTek, Inc. 186 Veterans Dr. Northvale, NJ 07647 USA
Factory ..... :	GlobTek (Suzhou) Co., Ltd Building 4, No. 76 JinLing East Road, Suzhou Industrial Park, Suzhou, JiangSu, 215021, China
Remarks for acceptance and review work conducted by above qualified testing laboratory	
Sample Number reviewed..... :	1 pcs

Remark ..... :	The product and the mentioned test reports comply with Swedish standard and nationals' 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-87772
Issued date..... :	2017-07-24
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 ..... :	GlobTek (Suzhou) Co., Ltd
	Building 4, No. 76, Jin Ling East Rd., Suzhou Industrial Park, Suzhou, JiangSu 215121, China
Technical data..... :	Input: 100-240V~, 50-60Hz, 0.45A
	Output: 5.0-5.5Vdc, Max.16W
Referred standard..... :	The requirements of USA and Canada have been also checked and found to include no national differences or deviations from the IEC 60601-1-11:2015
Model and/or type reference ..... :	GT*46161-**-USB
Involved test report ..... :	170500749SHA-002

GT*46161-**-USB
The 1st “*” can be “M” or “-“or “H” for market identification and not related to safety.
The 2nd “*” denote the rated output wattage designation, which can be “01” to “16”, with interval of 1.
The 3rd “*” denote the standard rated output voltage designation, which can be “5.0” to “5.5” or “05” to “05.5” with interval of 0.1.

Object/part No.	Manufacturer/ trademark	Type/model	Technical data	Standard (Edition / year)	Mark(s) of conformity[1])
Enclosure	SABIC	SE1X, SE1, SE100	Min. V-1, min. 1,5mm thick, 105°C	Applicable parts of IEC 60601-1, UL94	UL E45329
Alt. use	SABIC	C2950	Min. V-0, at min. 1.5mm thick, 85°C	Applicable parts of IEC 60601-1, UL94	UL E45329
Alt. use	SABIC	CX7211 EXCY0098 945	Min. V-0 at min. 1,5 mm thickness, 90°C	Applicable parts of IEC 60601-1, UL94	UL E45329
Alt. use	TEIJIN	LN-1250P LN-1250G	Min. V-0 at min. 1,5 mm thickness, 125°C	Applicable parts of IEC 60601-1, UL94	UL E50075
Alt. use	CHI MEI Corporation	PA-765A	Min. V-1 at min. 1,5 mm thickness, 85°C	Applicable parts of IEC 60601-1, UL94	UL E56070
Alt. use	CHI MEI Corporation	PC-540	Min. V-1 at min. 1,5 mm thickness, 70°C	Applicable parts of IEC 60601-1, UL94	UL E56070
Alt. use	FORMOSA CHEMICALS & FIBRE CORP PLASTICS DIV	AC310(+)	Min. V-0 at min. 1,5 mm thickness, 90°C	Applicable parts of IEC 60601-1, UL94	UL E162823
PCB	WALEX ELECTRONIC (WUXI) CO LTD	T2A T2B T4	Min. V-0, 130°C	Applicable parts of IEC 60601-1, UL94, UL 796	UL E154355
Alt. use	DONGGUAN HE TONG ELECTRONICS CO LTD	CEM1 2V0 FR4	Min. V-0, 130°C	Applicable parts of IEC 60601-1, UL94, UL 796	UL E243157
Alt. use	CHEERFUL ELECTRONIC	02 03 03A	Min. V-0, 130°C	Applicable parts of IEC 60601-1, UL94, UL 796	UL E199724
Alt. use	DAYSUN	DS2	Min. V-0, 130°C	Applicable parts of IEC 60601-1, UL94, UL 796	UL E251754
Alt. use	AREX	02V0,04V0	Min. V-0, 130°C	Applicable parts of IEC 60601-1, UL94, UL 796	UL E186016
Alt. use	BRITE PLUS ELECTRONICS (SUZHOU) CO LTD	DKV0-3A,DGV0-3A	Min. V-0, 130°C	Applicable parts of IEC 60601-1, UL94, UL 796	UL E177671
Alt. use	SHENZHEN TONGCHUANGXIN ELECTRONICS CO LTD	TCX	Min.V-0, 130°C	Applicable parts of IEC 60601-1, UL94, UL 796	UL E250336

Object/part No.	Manufacturer/ trademark	Type/model	Technical data	Standard (Edition / year)	Mark(s) of conformity[1])
Alt. use	PACIFIC WIN INDUSTRIAL LTD	PW-02 PW-03	Min.V-0, 130°C	Applicable parts of IEC 60601-1, UL94, UL 796	UL E228070
Alt. use	GOLDEN TRIANGLE PCB & TECHNOLOGIES LTD	GT-D	Min. 1,6 mm thickness, min. V-0, 130°C	IEC 60950-1 UL 796	Tested with appliance UL E340752
Alt. use	KUOTIANG ENT LTD	C-2 C-2A	Min.V-0, 130°C	Applicable parts of IEC 60601-1, UL94, UL 796	E227299
Alt. use	Various	Various	Min.V-0, 130°C	Applicable parts of IEC 60601-1, UL94, UL 796	UL approved
Fuse resistor (RF1) (optional)	ANHUI CHANGSHENG ELECTRONICS CO LTD	RXF21-1W	1Ω, 1W	IEC 60601-1 UL 248-1 UL 248-14	Tested with appliance UL E306095
Alt. use	SHENZHEN GREAT ELECTRONICS CO LTD	RXF-1W	1Ω, 1W	IEC 60601-1 UL 248-1 UL 248-14	Tested with appliance UL E301541
Alt. use	JIANGSU XINYANG ELECTRONIC COMPONENT CO LTD	RF10-1W	1Ω, 1W	IEC 60601-1 UL 248-1 UL 248-14	Tested with appliance UL E312842
Alt. use	SHENZHEN KAYOCOTA ELECTRONICS CO LTD	FRKNP-1WS	1Ω, 1W	IEC 60601-1 UL 248-1 UL 248-14	Tested with appliance UL E318056
Alt. use	ANHUI CHANGSHENG ELECTRONICS CO LTD	FRT-1W	1Ω, 1W	IEC 60601-1 UL 248-1 UL 248-14	Tested with appliance UL E306095
Alt. use	TZAI YUAN ENTERPRISE CO LTD	KNF1W	1Ω, 1W	IEC 60601-1 UL 248-1 UL 248-14	Tested with appliance UL E355632
Fuse (FS1)	Conquer Electronics Co., Ltd.	MST series	T1 A, 250 V, Rated breaking capacity 100A	IEC 60127-2	VDE 40017118 UL E82636
Alt.	Ever Island Electric Co., Ltd. And Walter Electric	2010	T1 A, 250 V, Rated breaking capacity 130A	IEC 60127-2	VDE 40018781 UL E220181
Alt.	Bel Fuse Ltd.	RST	T1AL, 250V, Rated breaking capacity 100A	IEC 60127-2	VDE 40011144 UL E20624
Alt.	Cooper Bussmann LLC	SS-5	T1AL, 250V, Rated breaking capacity 35A	IEC 60127-2	VDE 40015513 UL E19180

Object/part No.	Manufacturer/ trademark	Type/model	Technical data	Standard (Edition / year)	Mark(s) of conformity[1])
Alt.	Walter Electronic Co. Ltd.	ICP series	T1AL, 250V, Rated breaking capacity 50A	IEC 60127-2	VDE 40012824 UL E56092
Alt.	Shenzhen Lanson Electronics Co. Ltd.	SMT	T1AL, 250V, Rated breaking capacity 35A	IEC 60127-2	VDE 40012592 UL E221465
Alt.	Das & Sons International Ltd.	385T	T1AL, 250V, Rated breaking capacity 35A	IEC 60127-2	VDE 40008524 UL E205718
Y-Capacitor (CY1, CY2) (optional)	TDK-EPC Corporation, Capacitors Group Circuit Devices Business Group	CD	Y1, max. 1000 pF, min. 250 V	IEC/EN 60384-14 UL1414 (FOWX2)	VDE 138526 UL E37861
Alt. use	Success Electronics Co., Ltd.	SE	Y1, max. 1000 pF, min. 250 V	IEC/EN 60384-14 UL1414 (FOWX2)	VDE 40037211 VDE 40020002
Alt. use	Success Electronics Co., Ltd.	SB	Y1, AC250V, max 1000pF, 40/125/56/C	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40037221 VDE 40020001
Alt. use	Murata Mfg. Co., Ltd.	KX	Y1, max. 1000 pF, min. 250 V	IEC/EN 60384-14 UL1414 (FOWX2)	VDE 40002831 UL E37921
Alt. use	Walsin Technology Corp.	AH	Y1, max. 1000 pF, min. 250 V	IEC/EN 60384-14 UL1414 (FOWX2)	VDE 40001804 UL E146544
Alt. use	JYA-NAY Co., Ltd.	JN	Y1, max. 1000 pF, min. 250 V	IEC/EN 60384-14 UL1414 (FOWX2)	VDE 40001831 UL E201384
Alt. use	Haohua Electronic Co.	CT7	Y1, max. 1000 pF, min. 250 V	IEC/EN 60384-14 UL1414 (FOWX2)	VDE 40003902 UL E233106
Alt. use	Hongzhi Enterprises Ltd.	Y	Y1, max. 1000 pF, min. 250 V	IEC/EN 60384-14 UL1414 (FOWX2)	VDE 0004354 UL E192572
Alt. use	Jerro Electronics Corp.	JX series	Y1, max. 1000 pF, min. 250 V	IEC/EN 60384-14 UL1414 (FOWX2)	VDE 40032158 UL E333001
Transformer (T1)	GlobTek/ BOAM/ HAOPUWEI	XF01036	Class B	Applicable parts of IEC 60601-1	Tested in appliance
-Insulation system	CO LTD	130-1	Class B	Applicable parts of IEC 60601-1	UL E308897
Alt. use	GLOBTEK INC	GTX-130-TM	Class B	Applicable parts of IEC 60601-1	UL 243347

Object/part No.	Manufacturer/ trademark	Type/model	Technical data	Standard (Edition / year)	Mark(s) of conformity[1])
Alt. use	SHAN DONG BOAM ELECTRIC CO LTD	BOAM-01	Class B	Applicable parts of IEC 60601-1	UL E252329
Alt. use	WUXI HAOPUWEI ELECTRIC CO LTD	ZT-130	Class B	Applicable parts of IEC 60601-1	UL E315275
Transformer (T1) Secondary wire	GREAT LEOFLON INDUSTRIAL CO LTD	TRW(B)	Min.130°C	IEC/EN 60601-1	UL E211989
Alt. use	Cosmolink	TIW-M	Min.130°C	IEC/EN 60601-1	UL E213764
Alt. use	FUKUWARA	TEX-E	Min.130°C	IEC/EN 60601-1	UL E213764
Alt. use	Totoku	TIW-2	Min.130°C	IEC/EN 60601-1	UL E166483
Alt. use	SU ZHOU JIN YOU YU ELECTRONICS CO.,LTD	TAW-B	Min.130°C	IEC/EN 60601-1	E365319
Alt. use	E&B TECHNOLOGY CO LTD	E&B-XXXB E&B-XXXB-1	Min.130°C	IEC/EN 60601-1	UL E315265
Alt. use	CHANGYUAN ELECTRONICS (SHENZHEN) CO LTD	CB-TIW	Reinforced insulation, Class B	IEC 60950-1 UL 2353 UL 60601-1	Tested with appliance UL E249037
Alt. use	SHENZHEN JIUDING NEW MATERIAL CO LTD	DTIW-B	Reinforced insulation, Class B	IEC 60950-1 UL 2353 UL 60601-1	VDE 40037495 UL E357999
Bobbin of T1	Chang Chun	T375J, T375HF	V-0, 150°C, thickness 0,45 mm min.	Applicable parts of IEC 60601-1, UL94	UL E59481
Alt. use	Sumitomo Bakelite	PM-9820	V-0, 150°C, thickness 0,45 mm min.	Applicable parts of IEC 60601-1, UL94	UL E41429
Alt. use	HITACHI CHEMICAL CO LTD	CP-J-8800	V-0, 150°C, thickness 0,45 mm min.	Applicable parts of IEC 60601-1, UL94	UL E42956
Insulating tape of T1	3M Company	1350F-1, 1350T-1 44	Min. 130°C	Applicable parts of IEC 60601-1	UL E17385
Alt. use	BONDTEC PACIFIC CO.,LTD	370S	Min. 130°C	Applicable parts of IEC 60601-1	UL E175868
Alt. use	YAHUA	PZ series, CT series WF series	Min. 130°C	Applicable parts of IEC 60601-1	UL E165111
Alt. use	JINGJIANG JINGYI	JY25-A	Min. 130°C	Applicable parts of IEC 60601-1	UL E246950
Alt. use	Lang YI	LY-XX	Min. 130°C	Applicable parts of IEC 60601-1	UL E246820
Alt. use	SHEN ZHEN WEI CHUANG DA PACKAGING MATERIALS CO.,LTD.	W-001	Min. 130°C	Applicable parts of IEC 60601-1	E333581

Object/part No.	Manufacturer/ trademark	Type/model	Technical data	Standard (Edition / year)	Mark(s) of conformity[1])
Output cord	Various	Various	Min. 24AWG, min. 300V Min.80 degree	UL 758 IEC 60601-1	UL
Varistor (MOV1) (optional)	JOYIN CO LTD	10N471K14N471K	Max continuous voltage: 300VAC, 6kV/3kA, 40/85/56	IEC 61051-2UL 1449	VDE 005937 UL E325508
Alt. use	CENTRA SCIENCE CORP	10D471K14D471K	Max continuous voltage: 300VAC, 6kV/3kA, 40/85/56	IEC 61051-2UL 1449	VDE 40008220 UL E316325
Alt. use	THINKING ELECTRONIC INDUSTRIAL CO LTD	TVR10471KT VR14471K	Max continuous voltage: 300VAC, 6kV/3kA, 40/85/56	IEC 61051-2UL 1449	VDE 005944 UL E314979
Alt. use	SUCCESS ELECTRONICS CO LTD	SVR10D471K SVR14D471K	Max continuous voltage: 300VAC, 6kV/3kA, 40/85/56	IEC 61051-2UL 1449	VDE 40030401 UL E330256
Alt. use	CERAMATE TECHNICAL CO LTD	GNR10D471K GND14D471K	Max continuous voltage: 300VAC, 6kV/3kA, 40/85/56	IEC 61051-2UL 1449	VDE 40031745 UL E315429
Alt. use	BRIGHTKING (SHENZHEN) CO LTD	10D471K14D471K	Max continuous voltage: 300VAC, 6kV/3kA, 40/85/56	IEC 61051-2UL 1449	VDE 40027827 UL E327997

Supplementary information:

[1]) Provided evidence ensures the agreed level of compliance. See OD-CB2039.

For all transformers under all manufacturers.