


1.0 Reference and Address					
Report Number	170500750SHA-001	Original Issued:	27-Jun-2017	Revised:	24-Mar-2020
Standard(s)	<p>Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance [AAMI ES60601-1:2005 +A1]</p> <p>Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance [CSA C22.2#60601-1:2014 Ed.3]</p> <p>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 [IEC 60601-1-11:2015 Ed.2]</p>				
Applicant	GlobTek, Inc.	Manufacturer	GlobTek (Suzhou) Co., Ltd.		
Address	186 Veterans Dr. Northvale, NJ 07647	Address	Building 4. No 76 JinLing East Road, Suzhou Industrial Park, Suzhou, JiangSu, 215021		
Country	USA	Country	China		
Contact	Michael Krakovyak	Contact	Demon Zhou		
Phone	1.201.784.1000 x106	Phone	86 512 6279 0301 Ext.189		
FAX	1.201.784.0111	FAX	86 512 6279 0355		
Email	krakovyakm@globtek.us	Email	demon.zhou@globtek.cn		

2.0 Product Description	
Product	Medical Power Supply
Brand name	 GlobTek, Inc.
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. Transformers used in all models are with same construction. The turns of secondary winding may be added or reduced according different output voltage. All models have same PCB, but some non-critical components may be adjusted according different output voltage. The parameters of these components depend on output voltage.</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 as customer's request.</p>
Models	GT followed by M, - or H; followed by 46161-; followed by 01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 13, 14, 15 or 16; followed by 5.0, 5.1, 5.2, 5.3, 5.4, 5.5, 05, 05.1, 05.2, 05.3, 05.4 or 05.5; followed by -USB, -USB1A, -USB2A or -USBC.
Model Similarity	<p>M, - or H for market identification and not related to safety.</p> <p>01, 02, 03, 04, 05, 06, 07, 08, 09,10,11,12,13, 14, 15 or 16 denote the rated output wattage designation.</p> <p>5.0, 5.1, 5.2, 5.3, 5.4, 5.5, 05, 05.1, 05.2, 05.3, 05.4 or 05.5 denote the standard rated output voltage designation.</p> <p>-USB means Type 1 one USB type-A, -USB1A means Type 2 one USB type-A, -USB2A means Type 2 dual USB type-A and -USBC means Type 2 USB type-C.</p>
Ratings	<p>Input: 100-240 V~, 50-60 Hz, 0.45 A, Class II;</p> <p>Output: Refer to illustration No.1 for details.</p>
Other Ratings	N/A
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>Models GTM46161-165.0-USB and GTM46161-165.0-USBC are tested as typical models. Transformers used in all models are with same construction. The turns of secondary winding may be added or reduced according different output voltage. All models have same PCB, but some non-critical components may be adjusted according different output voltage. The parameters of these components depend on output voltage.</p> <p>The products are not intended to use in environment which altitude exceed 5000 m.</p> <p>Scope of Power Supply evaluation defers the following clauses to be determined as part of the end product investigation:</p> <p>Clause 7.5 (Safety Signs),</p> <p>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.),</p> <p>Clause 8.11.5 (Mains Fuse with High Breaking Capacity),</p> <p>Clause 9 (ME Hazard), except 9.1 and 9.3 are evaluated,</p> <p>Clause 10 (Radiation),</p> <p>Clause 11.7 (Biocompatibility),</p> <p>Clause 14 (PEMS),</p> <p>Clause 16 (ME Systems) ,</p> <p>Clause 17 (EMC)</p>

3.0 Product Photographs

Photo 1 - External view of EUT

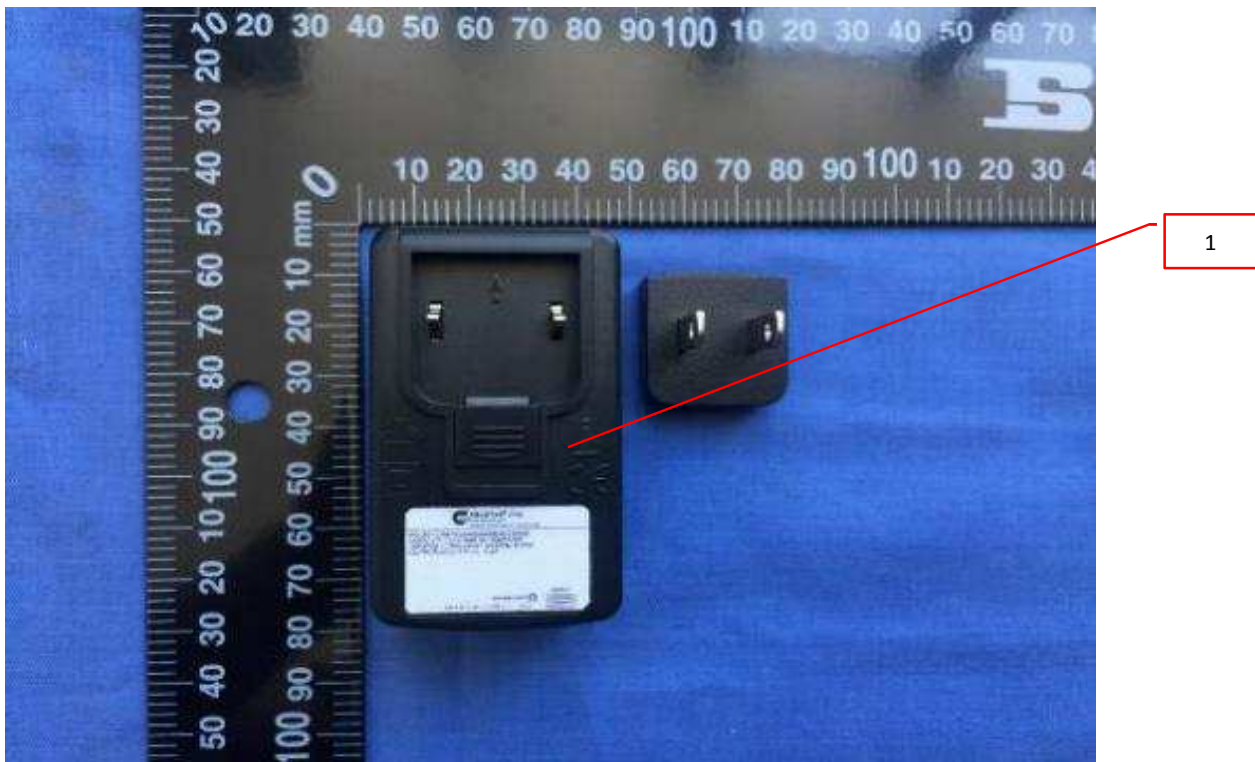
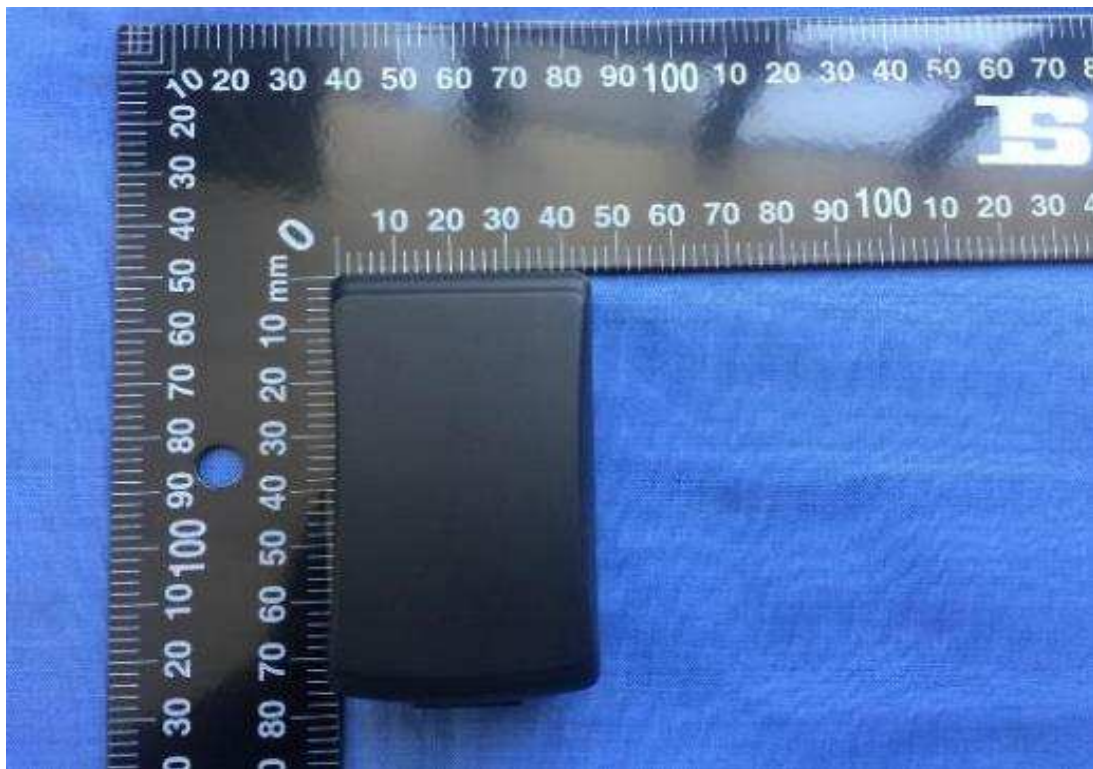


Photo 2 - External view of EUT

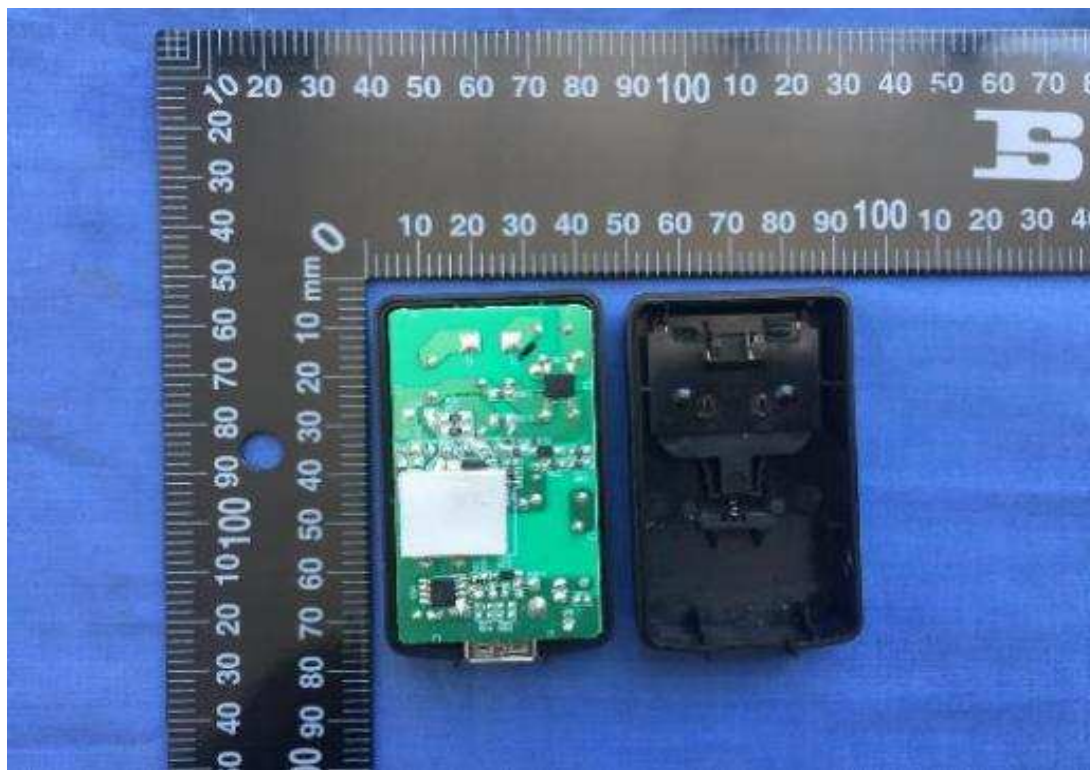


3.0 Product Photographs

Photo 3 - Internal view of EUT



Photo 4 - Internal view of EUT



3.0 Product Photographs

Photo 5 - Front view of PCB

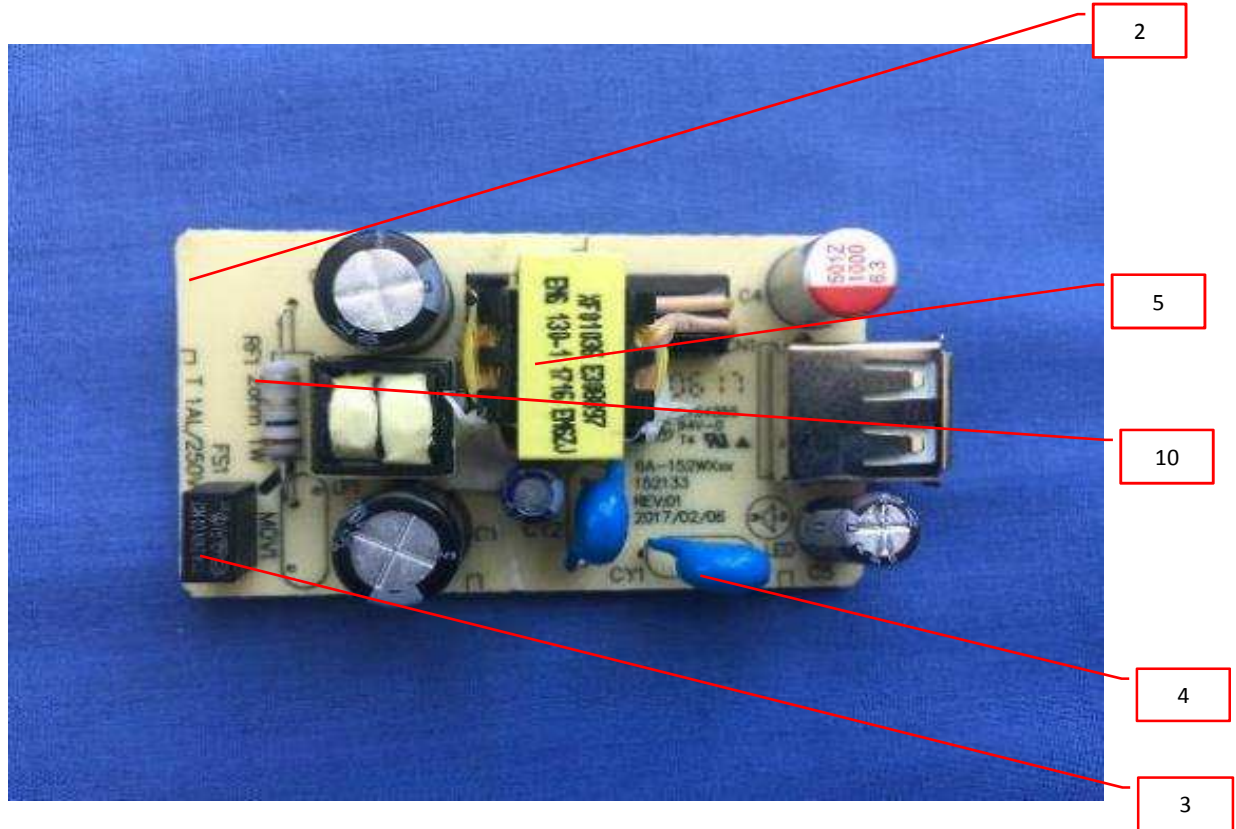
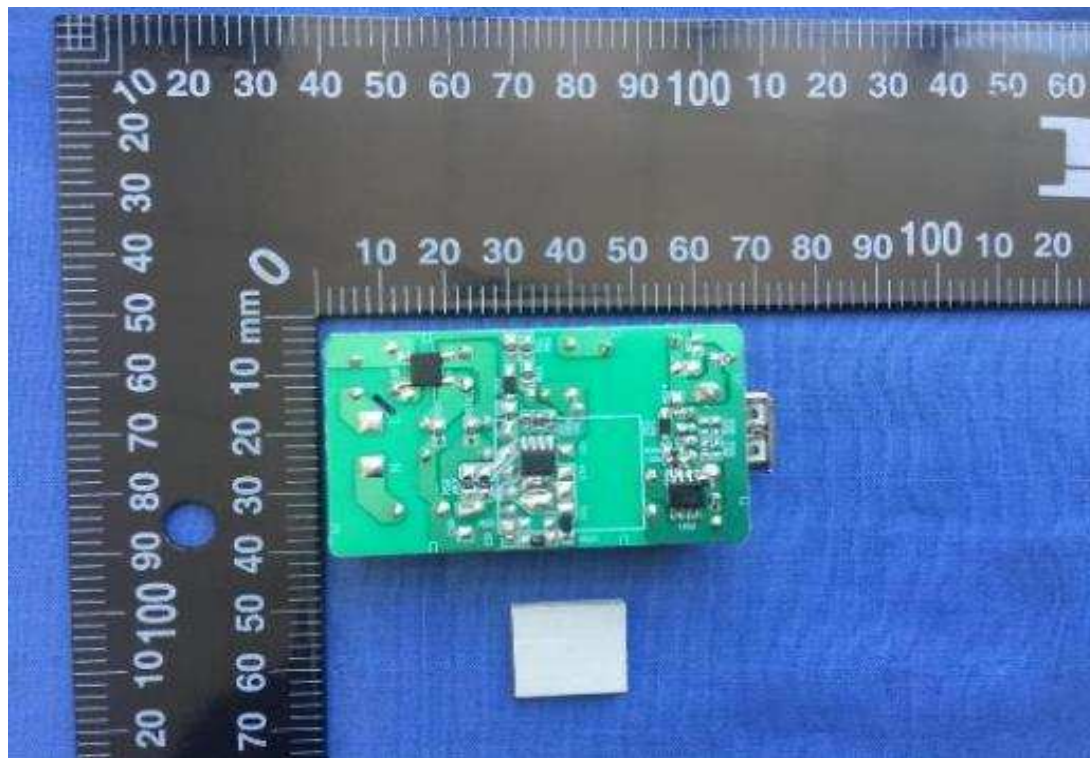


Photo 6 - Back view of PCB



3.0 Product Photographs

Photo 7 - External view of transformer

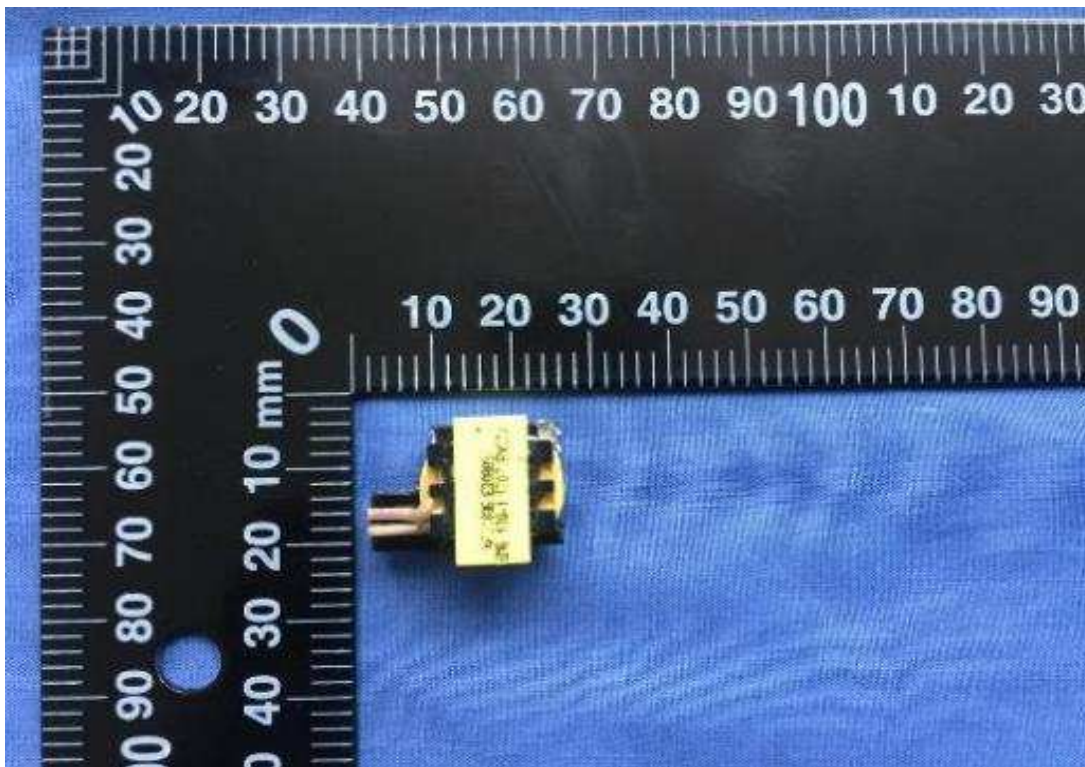
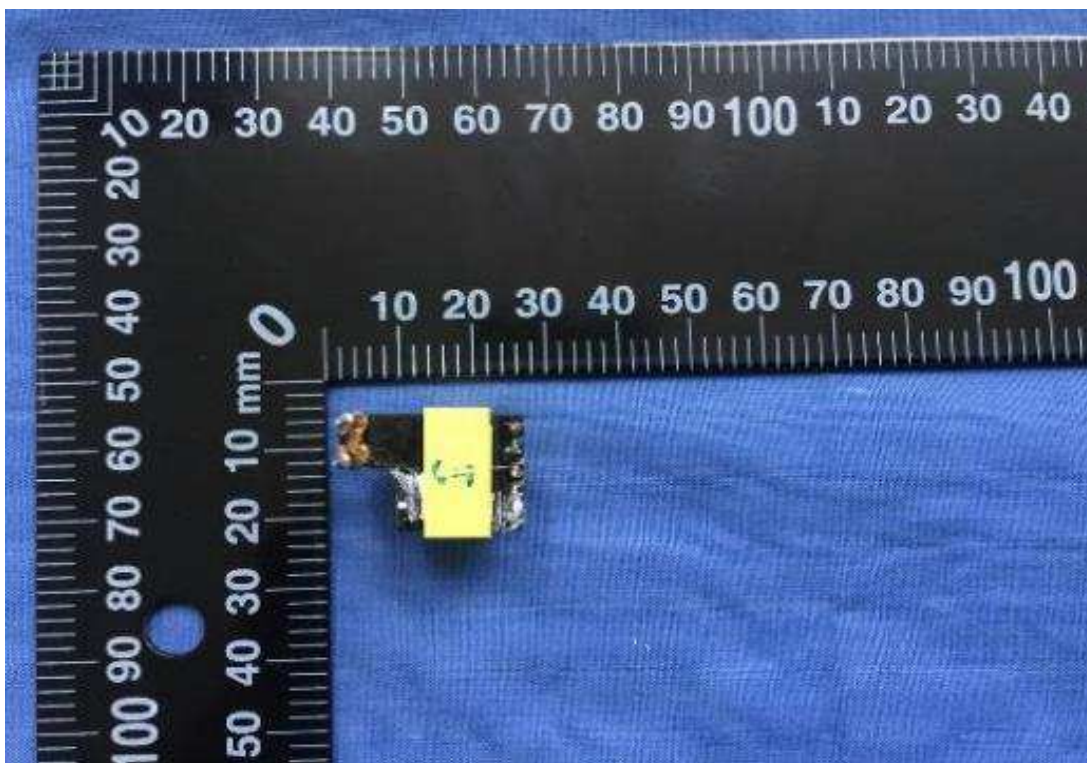
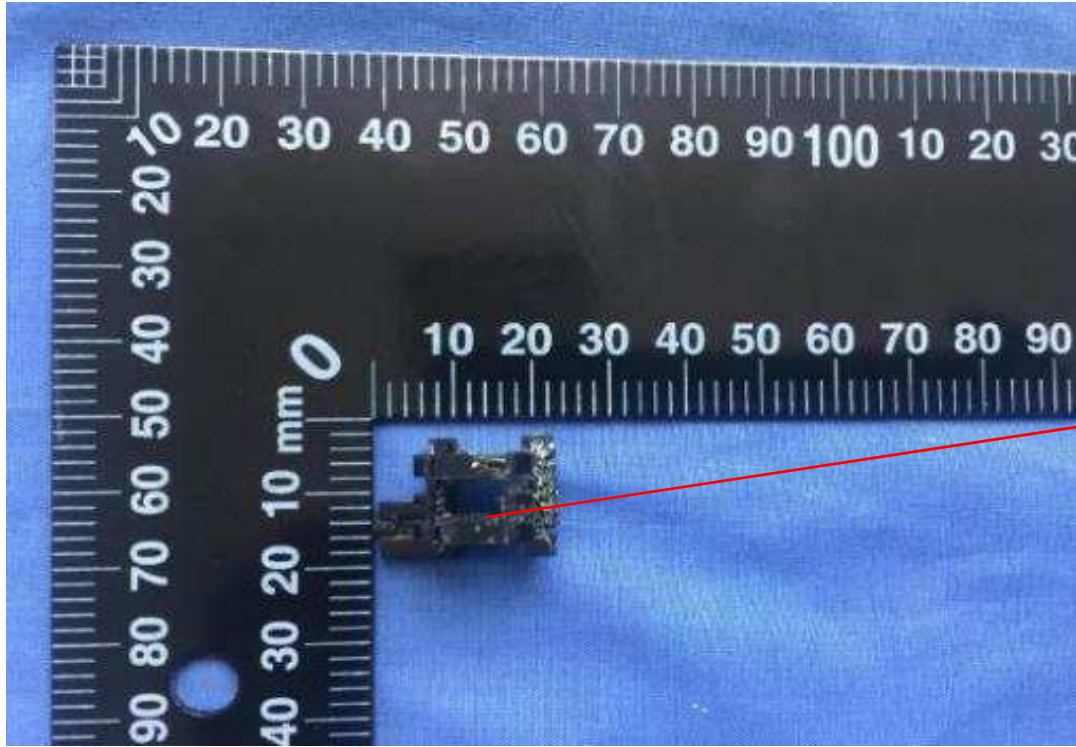


Photo 8 - External view of transformer



3.0 Product Photographs

Photo 9 - Internal view of transformer



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Photo 10 - External view of USB type-C port



3.0 Product Photographs

Photo 11 - External view of dual USB ports



Photo 12 - External view of one USB port

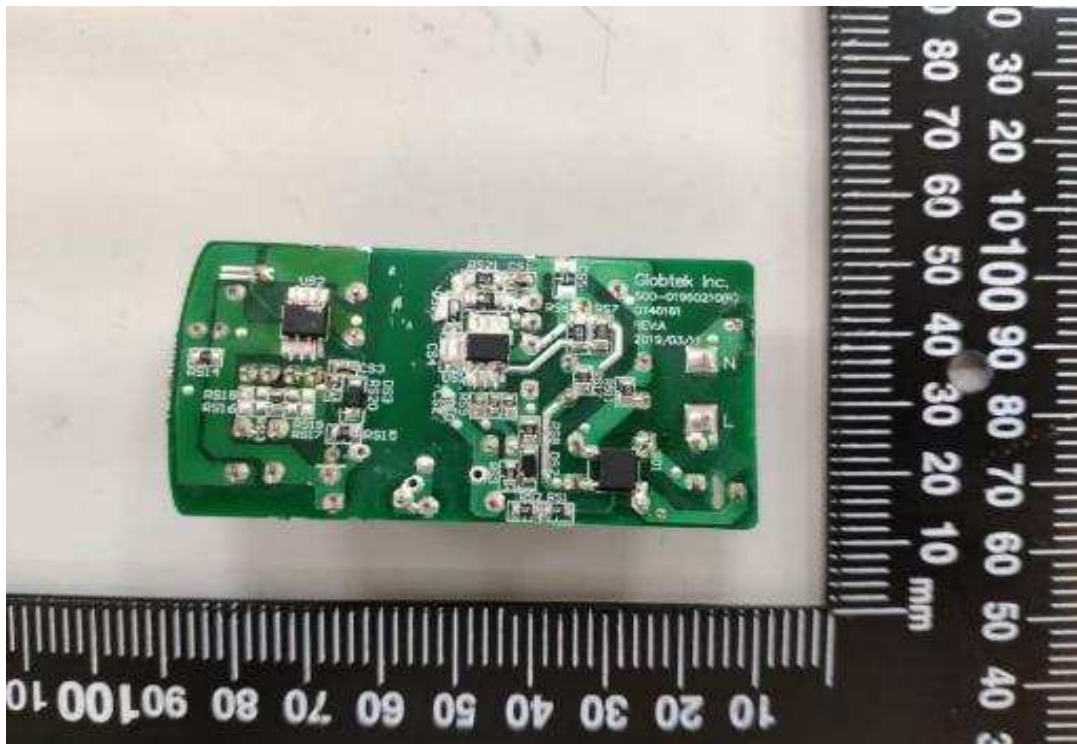


3.0 Product Photographs

Photo 13 - Top view of power board for USB type-C port



Photo 14 - Bottom view of power board for USB type-C port



3.0 Product Photographs

Photo 15 - Top view of power board for dual USB ports

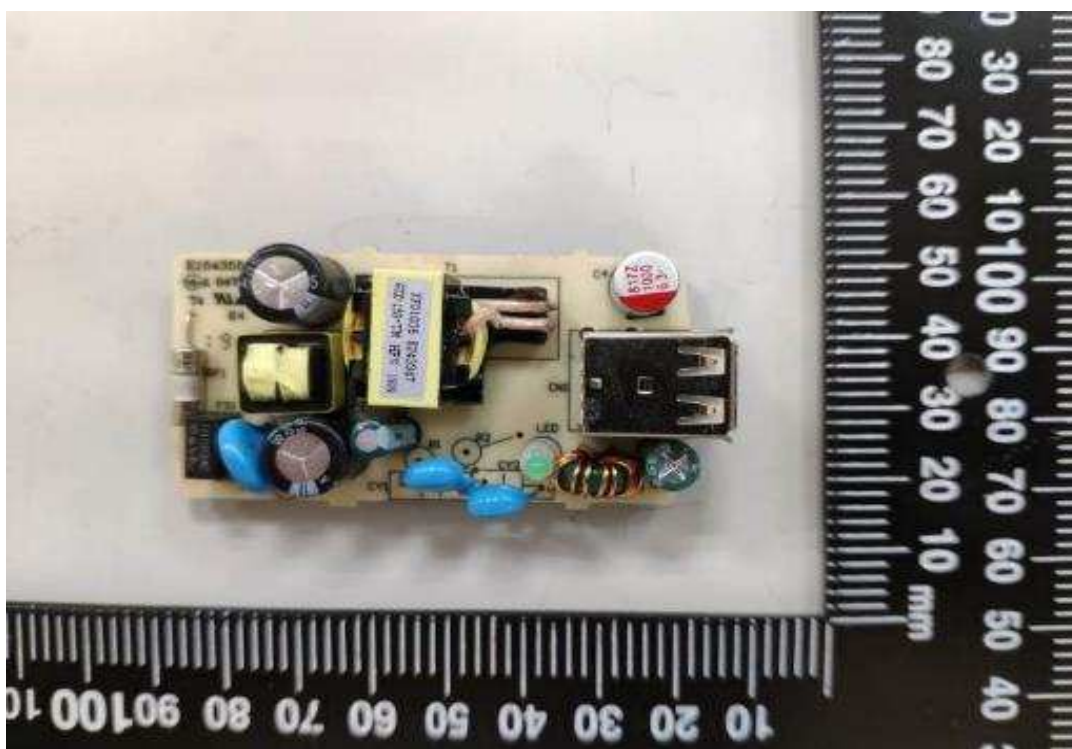
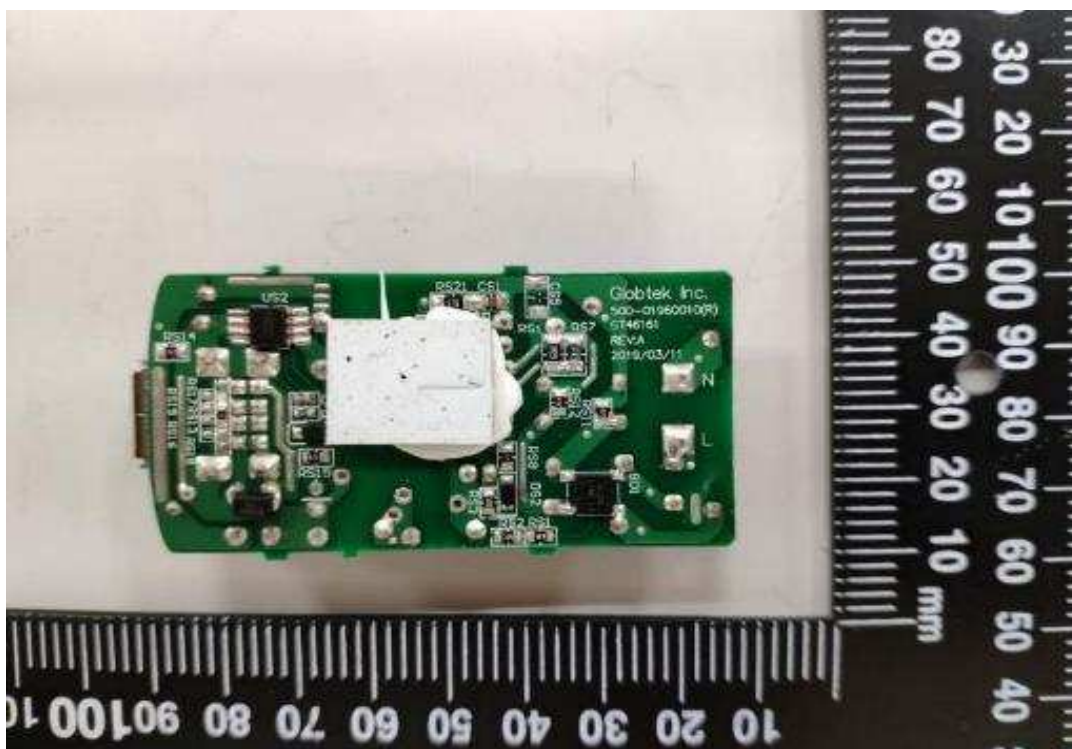


Photo 16 - Bottom view of power board for dual USB ports



3.0 Product Photographs

Photo 17 - Top view of power board for one USB port

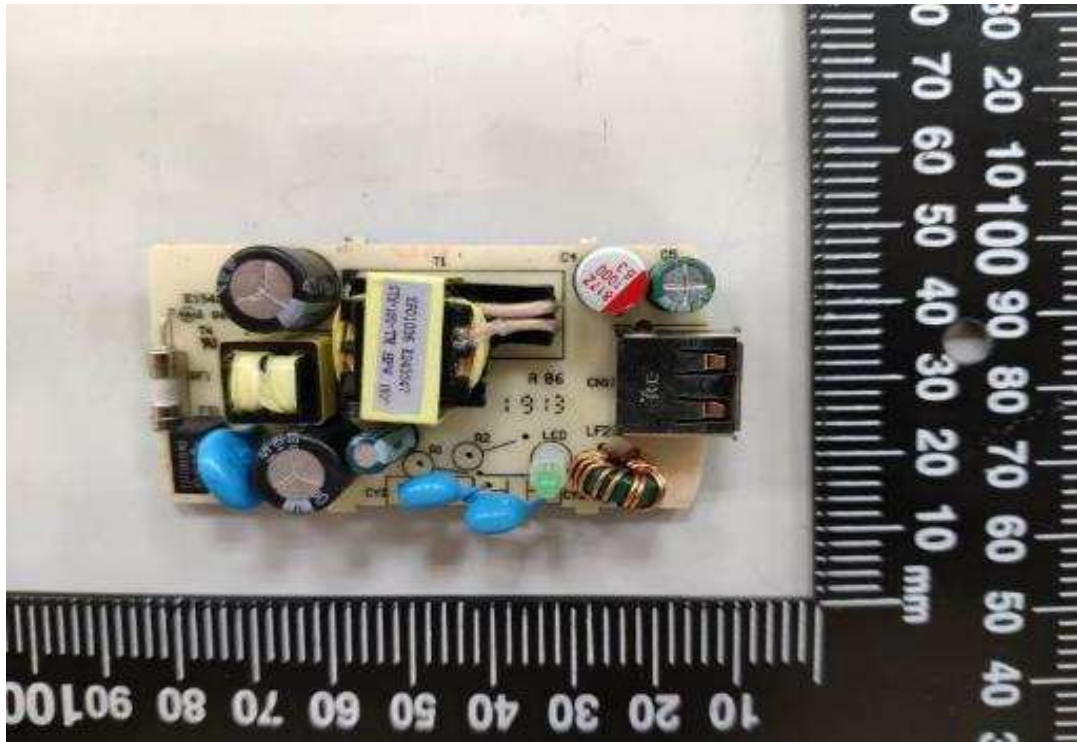


Photo 18 - Bottom view of power board for one USB port



4.0 Critical Components						
Photo #	Item no. ¹	Name	Manufacturer/ trademark ²	Type / model ²	Technical data and securement means	Mark(s) of conformity ³
1	1	Enclosure	SABIC	SE1X	Min. V-1 at 1.5 mm thickness 105°C	cURus
			SABIC	SE1	Min. V-1 at 1.5 mm thickness 105°C	
			SABIC	SE100	Min. V-1 at 1.5 mm thickness 105°C	
			SABIC	C2950	Min. V-0 at 1.5 mm thickness 85°C	
			SABIC	CX7211	Min. V-0 at 1.5 mm thickness 85°C	
			SABIC	EXCY0098	Min. V-0 at 1.5 mm thickness 85°C	
			SABIC	945	Min. V-0 at 1.5 mm thickness 85°C	
			TEIJIN	LN-1250P	Min. V-0 at 1.5 mm thickness 125°C	
			TEIJIN	LN-1250G	Min. V-0 at 1.5 mm thickness 125°C	
			CHI MEI Corporation	PA-765A	Min. V-1 at 1.5 mm thickness 85°C	
			FORMOSA CHEMICALS & FIBRE CORP PLASTICS DIV	AC310(+)	Min. V-0 at min. 1,5 mm thickness, 90°C	
5	2	PCB	WALEX ELECTRONIC (WUXI) CO LTD	T2A	Min. V-0, 130°C	cURus
			WALEX ELECTRONIC (WUXI) CO LTD	T2B	Min. V-0, 130°C	
			WALEX ELECTRONIC (WUXI) CO LTD	T4	Min. V-0, 130°C	
			DONGGUAN HE TONG ELECTRONICS CO LTD	CEM1	Min. V-0, 130°C	
			DONGGUAN HE TONG ELECTRONICS CO LTD	2V0	Min. V-0, 130°C	
			DONGGUAN HE TONG ELECTRONICS CO LTD	FR4	Min. V-0, 130°C	
			CHEERFUL ELECTRONIC	02	Min. V-0, 130°C	
			CHEERFUL ELECTRONIC	03	Min. V-0, 130°C	
			CHEERFUL ELECTRONIC	03A	Min. V-0, 130°C	
			DAYSUN	DS2	Min. V-0, 130°C	

4.0 Critical Components						
Photo #	Item no. ¹	Name	Manufacturer/ trademark ²	Type / model ²	Technical data and securement means	Mark(s) of conformity ³
			AREX	02V0	Min. V-0, 130°C	
				04V0		
				03V0		
			BRITE PLUS ELECTRONICS (SUZHOU) CO LTD	DKV0-3A	Min. V-0, 130°C	
				DGV0-3A		
			SHENZHEN TONGCHUANGXIN ELECTRONICS CO LTD	TCX	Min.V-0, 130°C	
			PACIFIC WIN INDUSTRIAL LTD	PW-02	Min.V-0, 130°C	
				PW-03		
			GOLDEN TRIANGLE PCB & TECHNOLOGIES LTD	GT-D	Min. 1,6 mm thickness, min. V-0, 130°C	
KUOTIANG ENT LTD	C-2	Min.V-0, 130°C				
	C-2A					
Various	Various	Min.V-0, 130°C				
5	3	Fuse (FS1)	Conquer Electronics Co., Ltd.	MST series	T1AL or T2AL, 250V, Rated breaking capacity 100A	cURus
			Ever Island Electric Co., Ltd. and Walter Electric	2010	T1AL or T2AL, 250V, Rated breaking capacity 130A	
			Bel Fuse Ltd.	RST	T1AL or T2AL, 250V, Rated breaking capacity 100A	
			Cooper Bussmann LLC	SS-5	T1AL or T2AL, 250V, Rated breaking capacity 35A	
			Walter Electronic Co. Ltd.	ICP series	T1AL or T2AL, 250V, Rated breaking capacity 50A	
			Shenzhen Lanson Electronics Co. Ltd.	SMT	T1AL or T2AL, 250V, Rated breaking capacity 35A	
			Das & Sons International Ltd.	385T series	T1AL or T2AL, 250V, Rated breaking capacity 35A	
			Zhongshan Lanbao Electrical Appliances Co., Ltd.	RTI-10 series	T1AL or T2AL, 250V, Rated breaking capacity 35A	

4.0 Critical Components						
Photo #	Item no. ¹	Name	Manufacturer/ trademark ²	Type / model ²	Technical data and securement means	Mark(s) of conformity ³
5	4	Y-Capacitor (CY1, CY2) (optional)	TDK-EPC Corporation, Capacitors Group Circuit Devices Business Group CORPORATION	CD	Y1, max. 1000 pF, min. 250 V	cURus
			SUCCESS ELECTRONICS CO LTD	SE	Y1, max. 1000 pF, min. 250 V	
			SUCCESS ELECTRONICS CO LTD	SB	Y1, AC250V, max 1000pF, 40/125/56/C	
			MURATA MFG CO LTD	KX	Y1, max. 1000 pF, min. 250 V	
			WALSIN TECHNOLOGY CORP	AH	Y1, max. 1000 pF, min. 250 V	
			JYA-NAY CO LTD	JN	Y1, max. 1000 pF, min. 250 V	
			HAOHUA ELECTRONIC CO	CT7	Y1, max. 1000 pF, min. 250 V	
			HONGZHI ENTERPRISES LTD	Y	Y1, max. 1000 pF, min. 250 V	
			JERRO ELECTRONICS CORP	JX-series	Y1, max. 1000 pF, min. 250 V	
5	5	Transformer (T1)	GlobTek	XF01036	Class B	NR
			ENG			
			BOAM			
			HAOPUWEI			
7	6	Transformer (T1) Secondary wire(not shown)	GREAT LEOFLON INDUSTRIAL CO LTD	TRW(B)	Min.130°C	cURus
			Cosmolink	TIW-M	Min.130°C	
			FUKUWARA	TEX-E	Min.130°C	
			Totoku	TIW-2	Min.130°C	
			SU ZHOU JIN YOU YU ELECTRONICS CO.,LTD	TAW-B	Min.130°C	
			E&B TECHNOLOGY CO LTD	E&B-XXXB E&B-XXXB-1	Min.130°C	

4.0 Critical Components						
Photo #	Item no. ¹	Name	Manufacturer/ trademark ²	Type / model ²	Technical data and securement means	Mark(s) of conformity ³
			CHANGYUAN ELECTRONICS (SHENZHEN) CO LTD	CB-TIW	Reinforced insulation, Class B	
			SHENZHEN JIUDING NEW MATERIAL CO LTD	DTIW-B	Reinforced insulation, Class B	
9	7	Bobbin	CHANG CHUN PLASTICS CO LTD	T375J	V-0, 150°C, thickness 0.45 mm min.	cURus
				T375HF		
			SUMITOMO BAKELITE CO LTD	PM-9820		
			HITACHI CHEMICAL CO LTD	CP-J-8800		
7	8	Insulating tape of T1(not shown)	3M COMPANY ELECTRICAL MARKETS DIV (EMD)	1350F-1	Min.130°C	cURus
				1350T-1		
				44		
			BONDTEC PACIFIC CO LTD	370S		
			YAHUA PRESSURE SENSITIVE GLUE CO LTD	PZ series		
				CT series		
				WF series		
		JINGJIANG JINGYI ADHESIVE PRODUCT CO LTD	JY25-A			
		CHANG SHU LIANG YI TAPE INDUSTRY CO LTD	LY-XX			
		SHEN ZHEN WEI CHUANG DA PACKAGING MATERIALS CO.,LTD.	W-001			
7	9	Insulation system(not shown)	GlobTek, Inc	GTX-130-TM	Class B	cURus
			BOAM	BOAM-01		
			ENG	ENG130-1		
			WUXI HAOPUWEI ELECTRONICS CO LTD	ZT-130		

4.0 Critical Components						
Photo #	Item no. ¹	Name	Manufacturer/ trademark ²	Type / model ²	Technical data and securement means	Mark(s) of conformity ³
5	10	Fuse resistor (RF1) (optional)	ANHUI CHANGSHENG ELECTRONICS CO LTD	RXF21-1W	1Ω, 1W	cURus
			SHENZHEN GREAT ELECTRONICS CO LTD	RXF-1W		
			JIANGSU XINYANG ELECTRONIC COMPONENT CO LTD	RF10-1W		
			SHENZHEN KAYOCOTA ELECTRONICS CO LTD	FRKNP-1WS		
			ANHUI CHANGSHENG ELECTRONICS CO LTD	FRT-1W		
			TZAI YUAN ENTERPRISE CO LTD	KNF1W		
1	11	Output cord(not shown)	Various	Various	Min. 24AWG, min. 300V Min.80 degree C	cURus
5	12	Varistor (MOV1) (optional)(not shown)	JOYIN CO LTD	10N471K	Max continuous voltage: 300VAC, 6kV/3kA, 40/85/56	cURus
				14N471K	Max continuous voltage: 300VAC, 6kV/3kA, 40/85/56	
			CENTRA SCIENCE CORP	10D471K	Max continuous voltage: 300VAC, 6kV/3kA, 40/85/56	
				14D471K	Max continuous voltage: 300VAC, 6kV/3kA, 40/85/56	
			THINKING ELECTRONIC INDUSTRIAL CO LTD	TVR10471K	Max continuous voltage: 300VAC, 6kV/3kA, 40/85/56	
				TVR10471M	Max continuous voltage: 300VAC, 6kV/3kA, 40/125/56	
				TVR14471K	Max continuous voltage: 300VAC, 6kV/3kA, 40/85/56	
			SUCCESS ELECTRONICS CO LTD	SVR10D471K	Max continuous voltage: 300VAC, 6kV/3kA, 40/85/56	
				SVR14D471K	Max continuous voltage: 300VAC, 6kV/3kA, 40/85/56	
			CERAMATE TECHNICAL CO LTD	GNR10D471K	Max continuous voltage: 300VAC, 6kV/3kA, 40/85/56	
				GND14D471K	Max continuous voltage: 300VAC, 6kV/3kA, 40/85/56	
			BRIGHTKING (SHENZHEN) CO LTD	10D471K	Max continuous voltage: 300VAC, 6kV/3kA, 40/85/56	
				14D471K	Max continuous voltage: 300VAC, 6kV/3kA, 40/85/56	
			Success Electronics Co, Ltd.	SVR10D471K	40/125/56	

4.0 Critical Components						
Photo #	Item no. ¹	Name	Manufacturer/ trademark ²	Type / model ²	Technical data and securement means	Mark(s) of conformity ³
			Brightking Electronics Co., Ltd.	471KH10	40/125/56	
			Shantou High-New Technology Dev. Zone Songtian Enterprise Co., Ltd.	10D471K	40/125/56	

- 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.

5.0 Critical Unlisted CEC Components

No Unlisted CEC components are used in this report.

6.0 Critical Features
<p><u>Recognized Component</u> - 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.</p>
<p><u>Listed Component</u> - 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.</p>
<p><u>Unlisted Component</u> - 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.</p>
<p><u>Critical Features/Components</u> - 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.</p>
<p><u>Construction Details</u> - 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.</p>
<p>1. <u>Spacing</u> - Refer to illustration No(s) 2 for details.</p>
<p>2. <u>Mechanical Assembly</u> - 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.</p>
<p>3. <u>Corrosion Protection</u> - All ferrous metal parts are protected against corrosion by painting, plating or the equivalent.</p>
<p>4. <u>Accessibility of Live Parts</u> - For adapter models, all uninsulated live parts in primary circuitry are housed within a non-metallic enclosure constructed with no openings.</p>
<p>5. <u>Grounding</u> - This product is not provided with a means of grounding as it is double insulated for Class II model.</p>
<p>6. <u>Polarized Connection</u> - This product is provided with a polarized power supply connection.</p>
<p>7. <u>Internal Wiring</u> - No internal wiring used.</p>
<p>8. <u>Schematics</u> - Refer to Illustration No(s). 3-4c for schematics & PCB layout requiring verification during Field Representative Inspection Audits.</p>
<p>9. <u>Markings</u> - The product is marked as follows: applicant's name or brand name, model number, electrical ratings. Refer to Illustration No. 5 for details.</p>
<p>10. <u>Cautionary Markings</u> - Refer to illustrations No. 5 for details.</p>
<p>11. <u>Safety Instructions</u> - 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.</p>

7.0 Illustrations

Illustration 1 - Model list

Model	Rated output voltage range	Max. rated output current	Max. rated output power
GT*46161-*5.0-* GT*46161-*05-*	5 Vdc	3.2 A	16 W
GT*46161-**-* (The 3rd "" can be "5.1" to "5.5" or "05.1" to "05.5")	5.1-5.5 Vdc	3.14 A	16 W

7.0 Illustrations

Illustration 2 - Insulation diagram

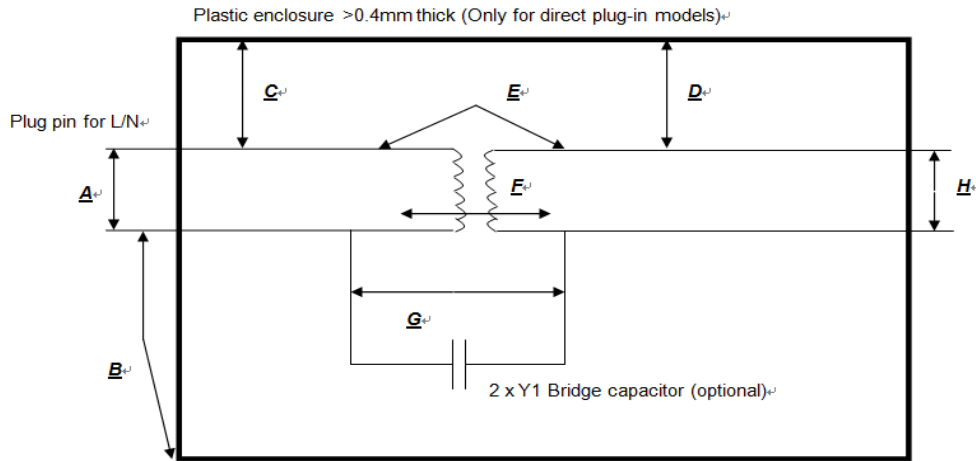



TABLE: INSULATION DIAGRAM									P	
Pollution degree									2	—
Overvoltage category									II	—
Altitude									Up to 5000m, use multiple factor 1.29 for MOPP, multiple factor 1.48 for MOOP	—
Additional details on parts considered as applied parts									<input checked="" type="checkbox"/> None <input type="checkbox"/> Areas _____ (See Clause 4.6 for details)	—
Area	Number and type of Means of Protection: MOOP, MOPP	CTI	Working voltage		Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks	
			V _{rms}	V _{pk}						
A	1MOOP	IIIb	240	--	3.0	3.0	3.7	3.7	Mains opposite polarity	
B	2MOPP	IIIb	240	--	8.0	6.5	8.2	8.2	Mains (plug pin) to enclosure (accessible position during normal use)	
C	2MOPP	IIIb	240	--	--	--	--	--	Mains to external of enclosure (>0.4mm thick plastic enclosure, solid insulation)	
D	2MOPP	IIIb	--	Max. 48	--	--	--	--	Secondary to external of enclosure (>0.4mm thick plastic enclosure, solid insulation)	
E	2MOPP	IIIb	240	352	8.0	6.5	9.0	9.0	Mains to secondary on PCB	
F	2MOPP	IIIb	240	352	8.0	6.5	9.0	9.0	Mains to secondary on transformer	
G	2MOPP	IIIb	240	352	8.0	6.5	10.5	10.5	Mains to secondary on bridge capacitors, see 8.5.1.2 and 8.8.3	
H	2MOPP	IIIb	--	Max. 48	--	--	--	--	Accessible part per 8.4.2c)	


7.0 Illustrations

Illustration 5 - Marking label

The other models (refer to 2.0) have the same labels except the model number and rating.

 **GlobTek, Inc.**
186 Veterans Dr.
Northvale, NJ 07647 USA
www.globtek.com
CLASS 2 POWER SUPPLY 电源供应器
P/N(料号):WR9QA3200USBNMEDR6W
MODEL(型号):GTM46161-165.0-USB
INPUT(输入):100-240V~,50-60Hz, 0.45A
OUTPUT(输出):5 V \equiv 3.2A,16W

WARNING/AVERTISSEMENT:
RISK OF ELECTRIC SHOCK
DRY LOCATION USE ONLY
FOR INDOOR USE ONLY
Risque de choc électrique
Utilisation endroit sec
Pour une utilisation en intérieur
See instructions if the input
plug does not fit the power outlet.


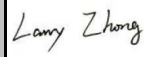
RECOGNIZED
COMPONENT

C LISTED US
Intertek
4007497
Conforms to AAMI STD.ES60601-1,IEC 60601-1-11
Certified to CAN/CSA STD.C22.2 NO.60601-1



8.0 Test Summary			
Evaluation Period	5/23/2017-6/5/2017		Project No. 170500750SHA
Sample Rec. Date	23-May-2017	Condition	Prototype
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 [AAMI ES60601-1:2005 +A1] Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance [CSA C22.2#60601-1:2014 Ed.3] 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		
Surfaces, corners and edges	9.3		
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		

Test Description	Medical Elec. Equip.- Part 1-11: Gen. Req. For Basic Safety & Essential Perf.- Collateral Standard - Req. For Medical Elec. Equip. & Medical Elec. Systems Used In The Home Healthcare Environment [IEC 60601-1-11:2015 Ed.2] Clause
Environmental condition test of transport and storage between uses	4.2.2
Continuous operating conditions	4.2.3.1
Shock test	10.1.2 a)
Vibration test	10.1.2 b)

8.0 Test Summary			
Evaluation Period	November 11, 2019 - January 10, 2020		Project No. TWJ19110010
Sample Rec. Date	23-Oct-2019	Condition	Prototype
			Sample ID. P190700180
Test Location	Intertek Testing Services Taiwan Ltd. (Taipei office) address: 5F, No. 423, Ruiguang Rd., Neihu District, Taipei 114, Taiwan		
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 construction review and testing record were conducted simultaneously with Report No.: 191000380TWN-001 and 191000382TWN-001.			
Test Description	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance [AAMI ES60601-1:2005 +A1] Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance [CSA C22.2#60601-1:2014 Ed.3] Clause		
Power Input	4.11		
Excessive Temperature	11.1		

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:	Viper Lai	Reviewed by:	Larry Zhong
Title:	Project Handler	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
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 Taiwan Limited
ETL Component Evaluation Center
5/F., No. 423, Ruiguang Road, Neihu District
Taipei 114, Taiwan
Attn: Sample Room

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

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>
For all models between mains part and secondary circuits	4000Vac	60 s

12.0 Revision Summary				
The following changes are in compliance with the declaration of Section 8.1:				
Date/ Proj # Site ID	Project Handler/ Reviewer	Section	Item	Description of Change
24-Mar-2020/ TWJ1911001 OTWN	Project Handler / Viper Lai <i>Viper L.</i>	1	-	Corrected address of applicant from "186 Veterans Dr. Northvale, NJ 07647 USA" to "186 Veterans Dr. Northvale, NJ 07647"; updated applicant contact from "Hans Moritz" to "Michael Krakovyak", phone no. from "(201)784-1000 Ext.253" to "1.201.784.1000 x106", fax no. from "(201)784-0111" to "1.201.784.0111", email from "Moritzh@globtek.com" to "krakovyakm@globtek.us".
	Reviewer / Larry Zhong <i>Larry Zhong</i>	2	-	Revised models from "GT followed by M, - or H; followed by 46161-; followed by 01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 13, 14, 15 or 16; followed by 5.0, 5.1, 5.2, 5.3, 5.4, 5.5, 05, 05.1, 05.2, 05.3, 05.4 or 05.5; followed by -USB." to "GT followed by M, - or H; followed by 46161-; followed by 01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 13, 14, 15 or 16; followed by 5.0, 5.1, 5.2, 5.3, 5.4, 5.5, 05, 05.1, 05.2, 05.3, 05.4 or 05.5; followed by -USB, -USB1A, -USB2A or -USBC."
		3	10-18	Added photos for the alternative types of USB output port
		4	1	Deleted PC-540 by Chi Mei Corporation
			2	Added 03V0 by AREX
			3	Revised T1AL to "T1AL or T2AL"
			3	Added alternate second sources
			12	Added alternate second sources
		6	8	Revised sentence from "refer to Illustration No(s). 3-4 for schematics & PCB layout" to "refer to Illustration No(s). 3-4c for schematics & PCB layout"
		7	1	Updated Model list
			3	Added circuits for the alternative types of USB output port
			4a, 4b, 4c	Added layouts for the alternative types of USB output port
			5	Updated label
		8	-	Updated test summary
	9	-	Corrected address of applicant from "186 Veterans Dr. Northvale, NJ 07647 USA" to "186 Veterans Dr. Northvale, NJ 07647".	