

1.0 Reference and Address			
Report Number	171201811SHA-001	Original Issued:	31-Mar-2018
		Revised:	None
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 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]</p>		
Applicant	GlobTek, Inc.	Manufacturer	GlobTek (Suzhou) Co., Ltd.
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2.0 Product Description	
Product	Medical Power Supply
Brand name	GlobTek
Description	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. All the types are designed for continuous operation and no applied part is defined. The insulation construction of EUT is evaluated as 2MOPP in this report as customer's request.
Models	GT followed by M, - or H; followed by 86100-; followed by 01 to 10; followed by 05, 05.1, 05.2, 5.0, 5.1 or 5.2; followed by -W2; may be followed by -USB. GT followed by M, - or H; followed by 86100-; followed by 01 to 10; followed by 05, 05.1, 05.2, 5.0, 5.1 or 5.2; followed by -W2; may be followed by -USB.
Model Similarity	GT*86100-**-W2* The 1st "*" part can be 'M' or '-' or 'H' for market identification and not related to safety. The 2nd "*" denotes the rated output wattage designation, which can be "01" to "10", with interval of 1 The 3rd "*" denotes the rated output voltage designation, which can be "5.0", "5.1", "5.2" or "05", "05.1", "05.2". The 4th "*" can be "-USB" or blank, -USB denote the power supplies use USB port, when it is blank, denote the power supplies use DC output wires.
Ratings	Input: 100-240V~, 50-60Hz, 0.3A Output: 5-5.2VDC, Max.2A Max 10W
Other Ratings	NA

2.0 Product Description

Conditions of Acceptability	<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. The turns of secondary winding may be added or reduced according different output voltage. All models have similar 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>
	<p>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 5000m.</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 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(GTM86100-1005-W2-USB)

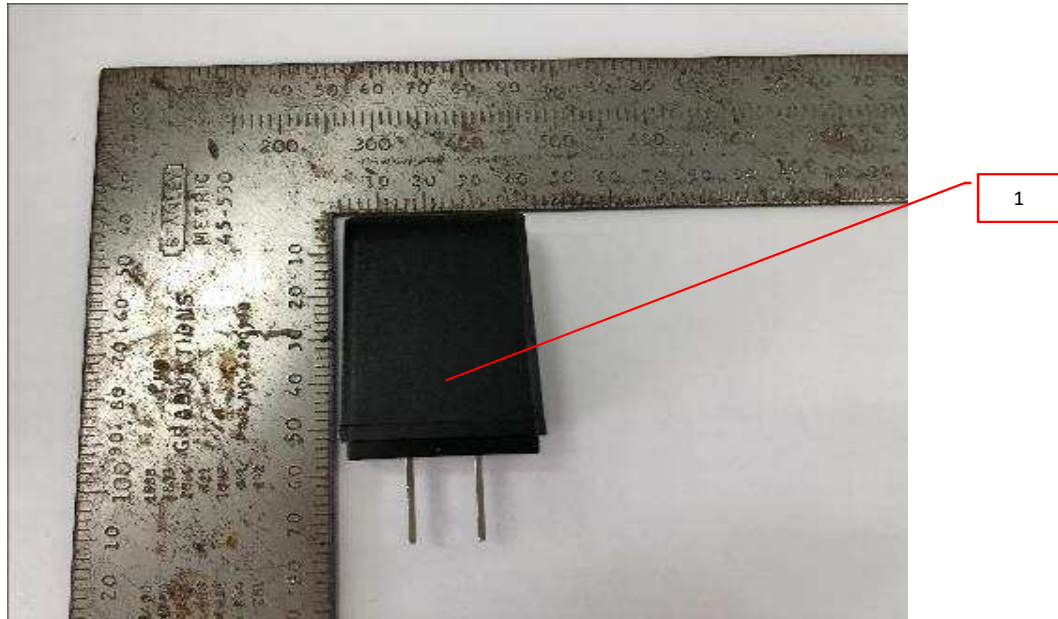
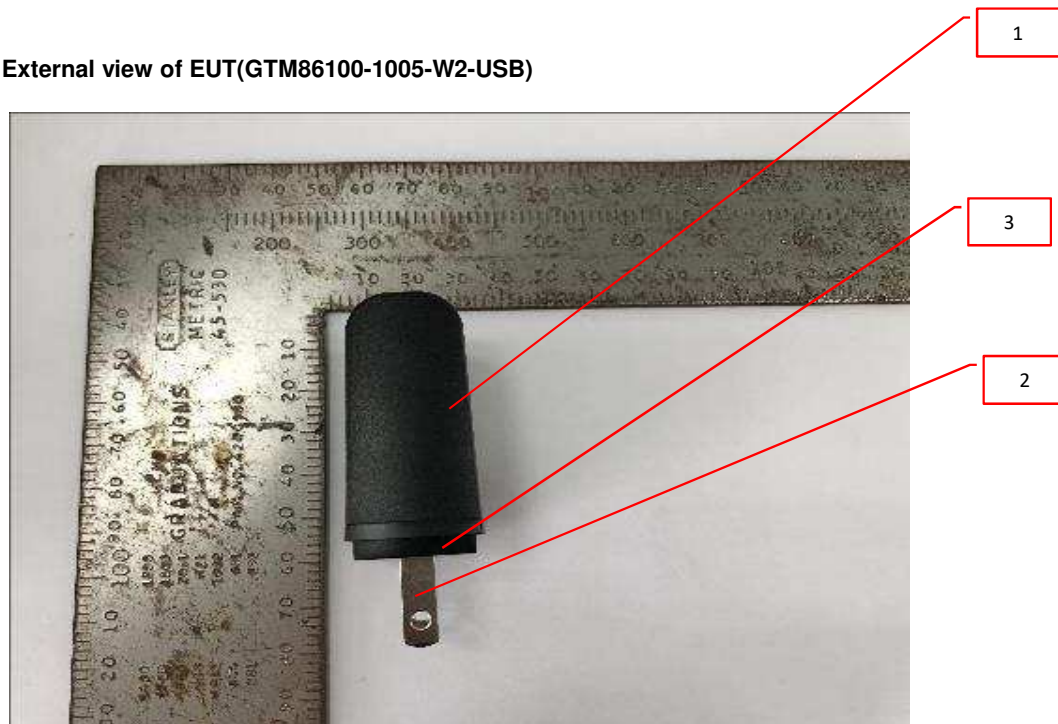


Photo 2 - External view of EUT(GTM86100-1005-W2-USB)

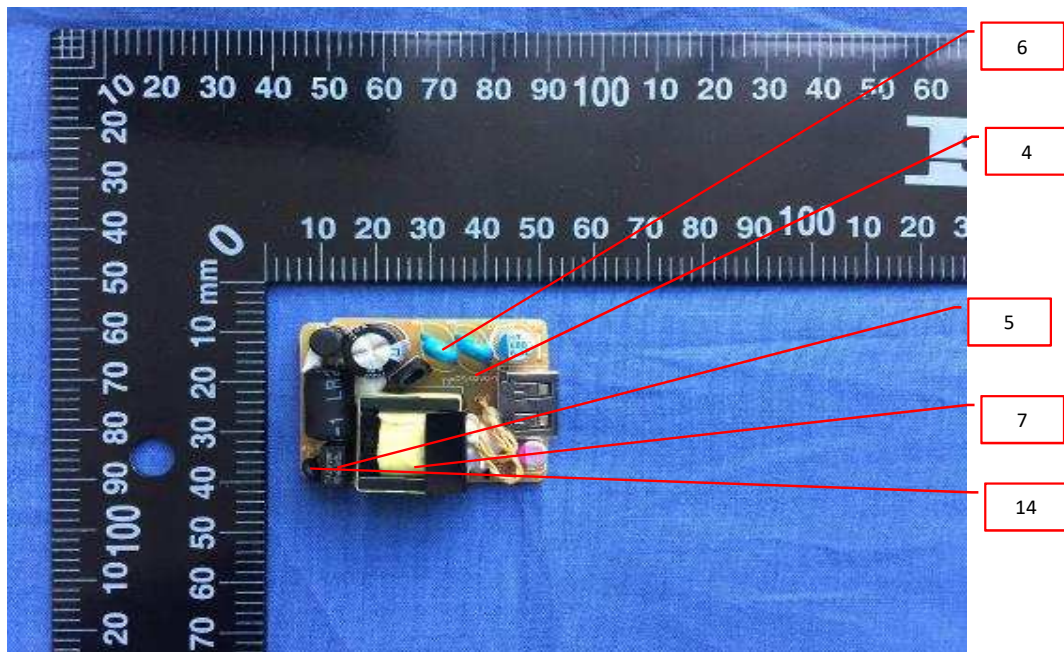


3.0 Product Photographs

Photo 3 - External view of EUT(GTM86100-1005-W2-USB)



Photo 4 - Internal view of EUT(GTM86100-1005-W2-USB)



3.0 Product Photographs

Photo 5 - Internal view of EUT(GTM86100-1005-W2-USB)

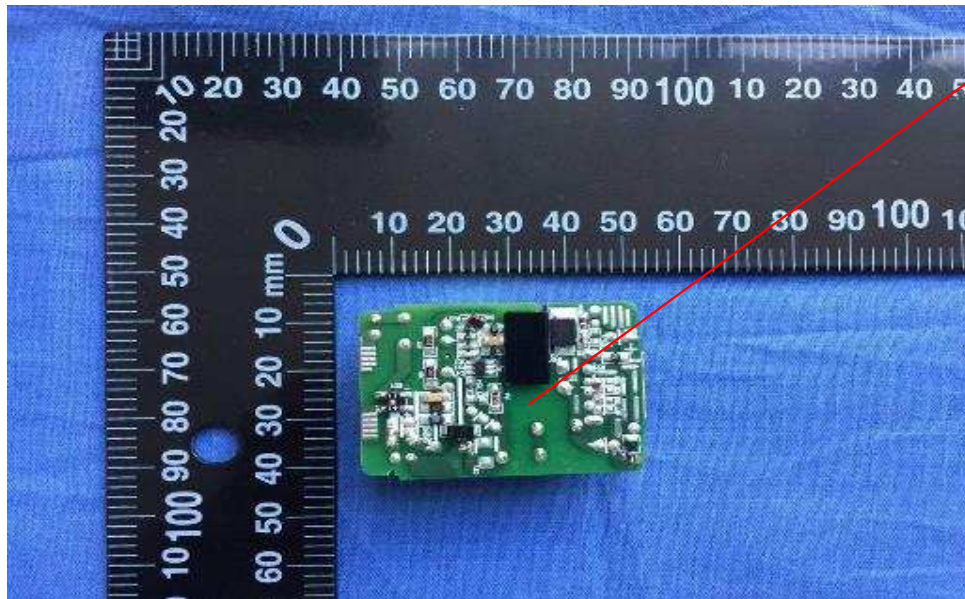
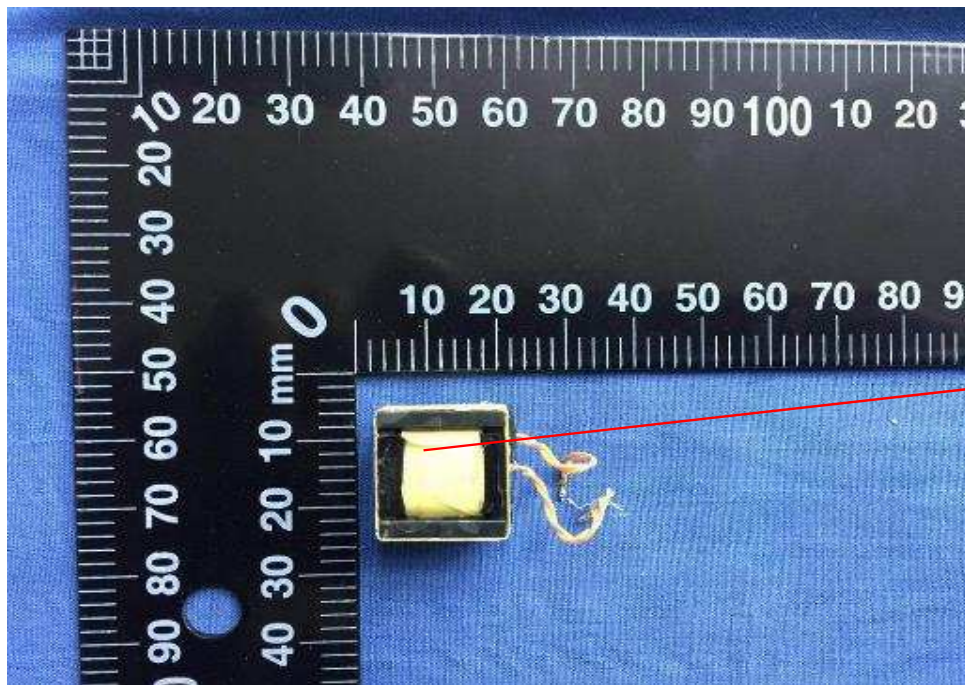


Photo 6 - External view of transformer



3.0 Product Photographs

Photo 7 - External view of transformer

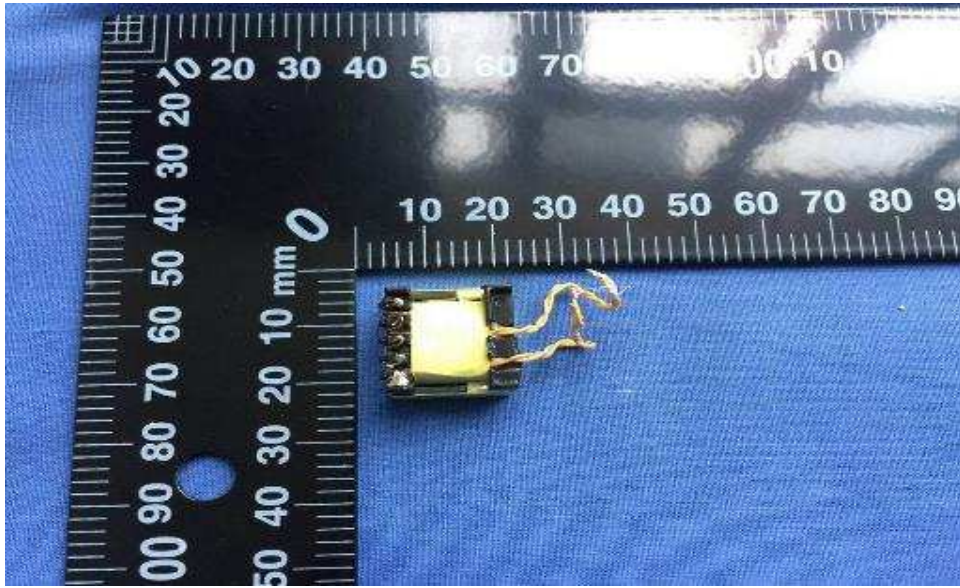
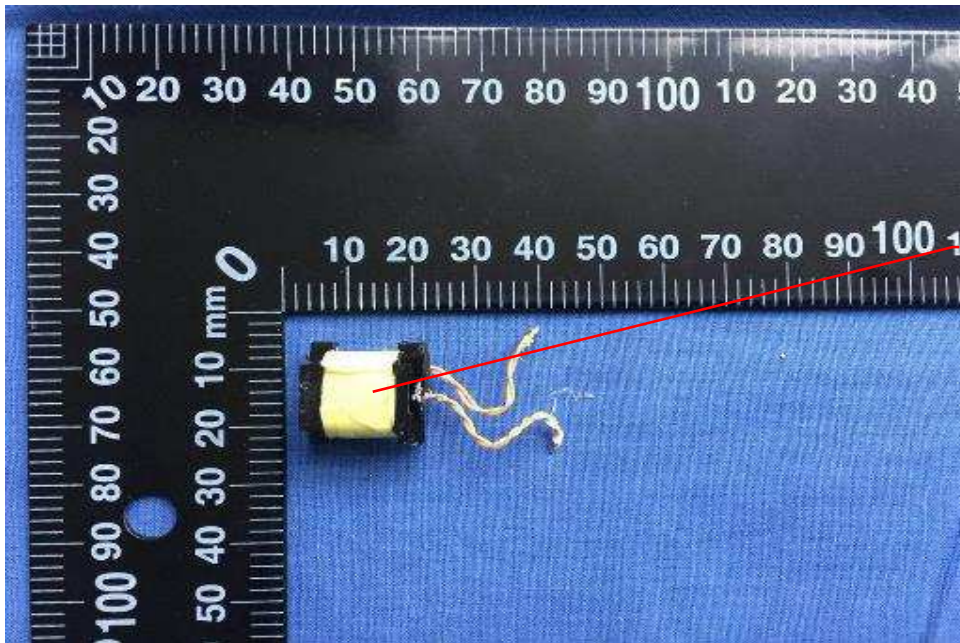


Photo 8 - Transformer



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3.0 Product Photographs

Photo 9 - Primary winding view of mains transformer

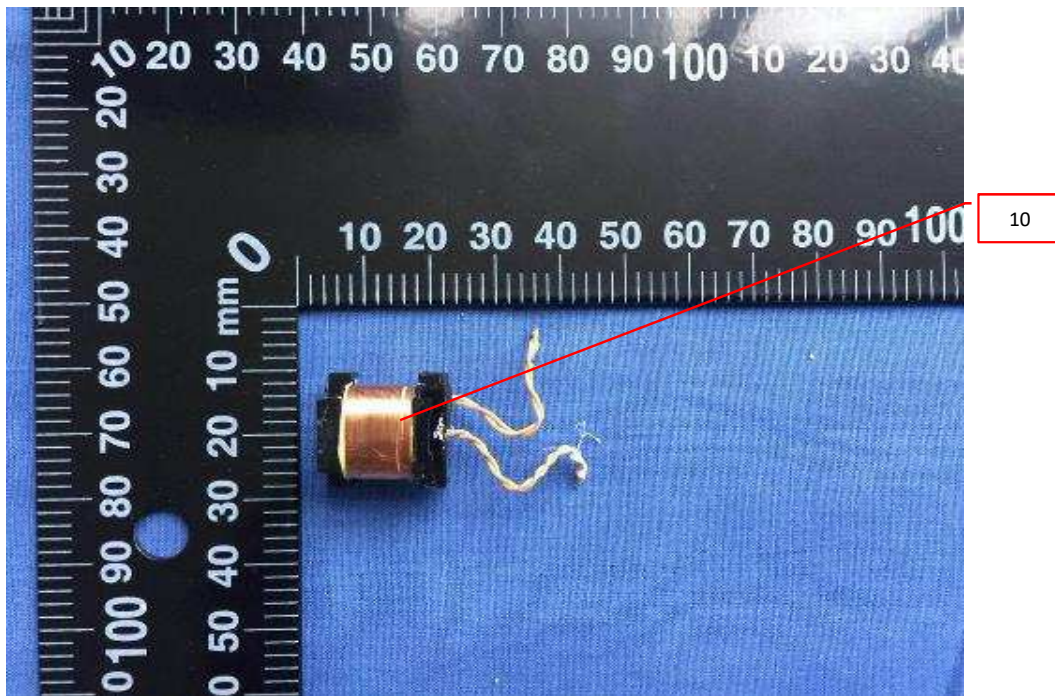
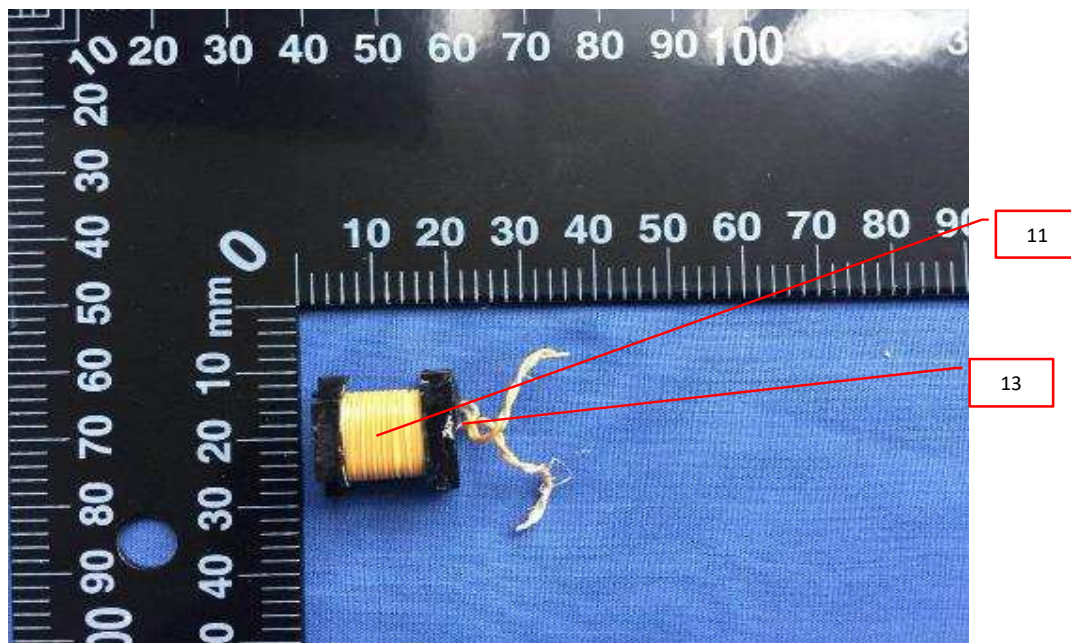


Photo 10: Secondary winding view of mains transformer (TIW)



3.0 Product Photographs

Photo 11: Transformer

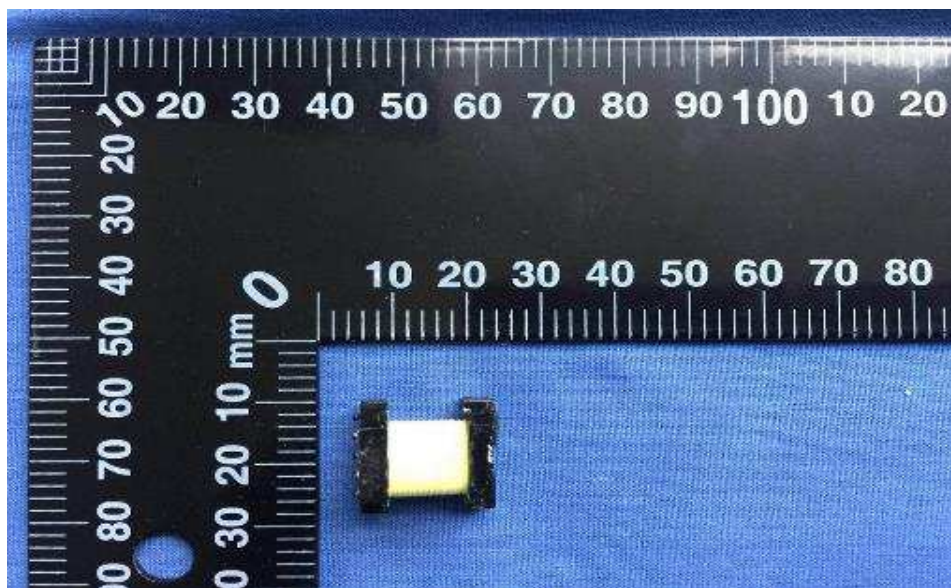
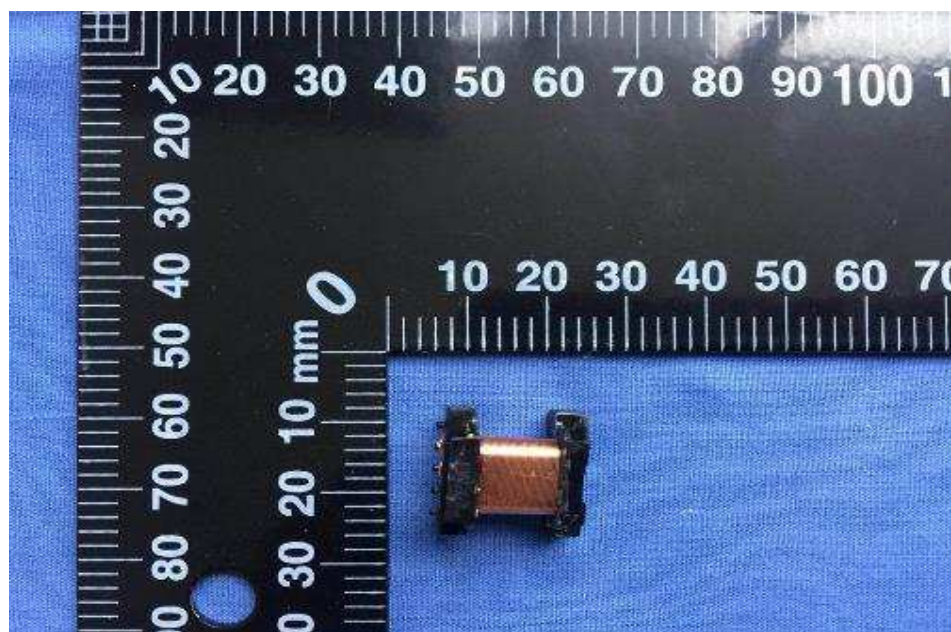


Photo 12: Transformer



3.0 Product Photographs

Photo 13: Bobbin view of transformer

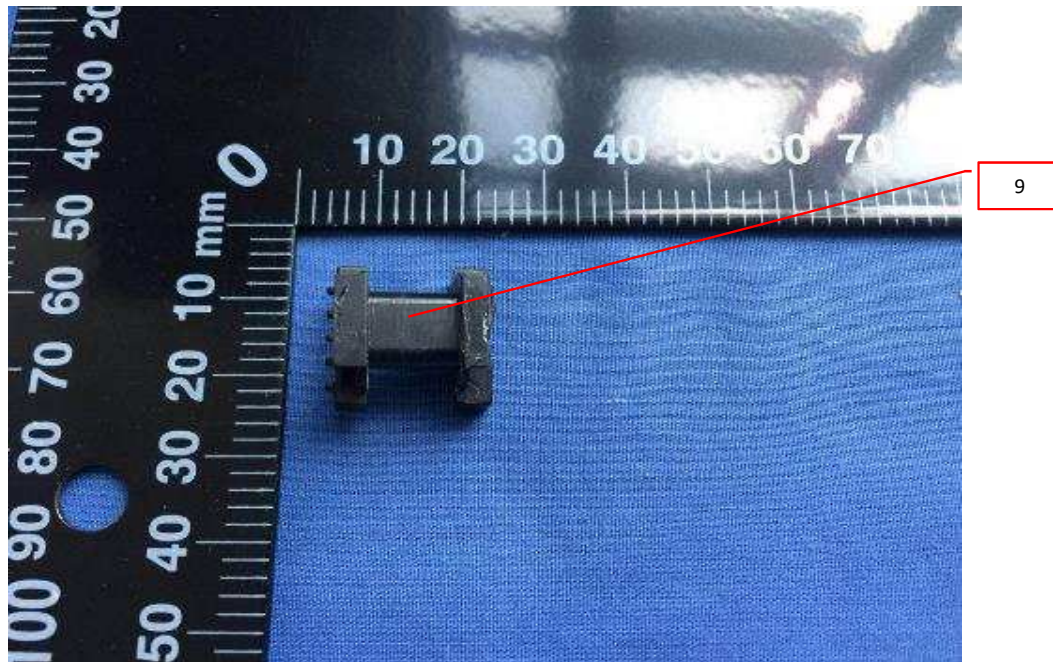


Photo 14: External view of EUT (GTM86100-1005-W2)



3.0 Product Photographs

Photo 15: External view of EUT (GTM86100-1005-W2)



Photo 16: External view of EUT (GTM86100-1005-W2)



3.0 Product Photographs

Photo 17: Internal view of EUT (GTM86100-1005-W2)

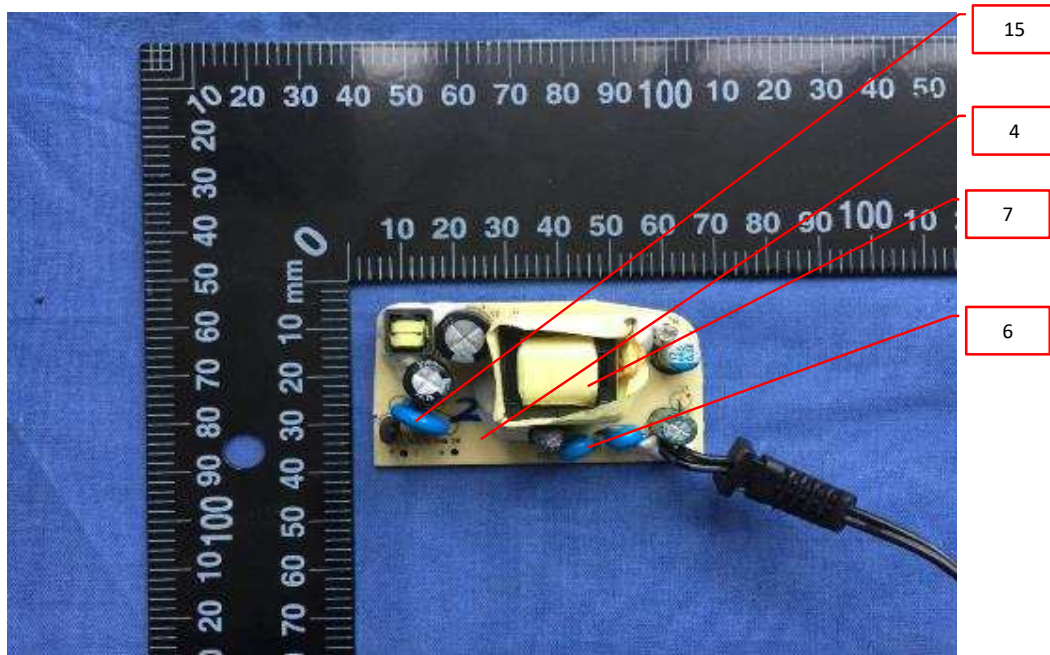
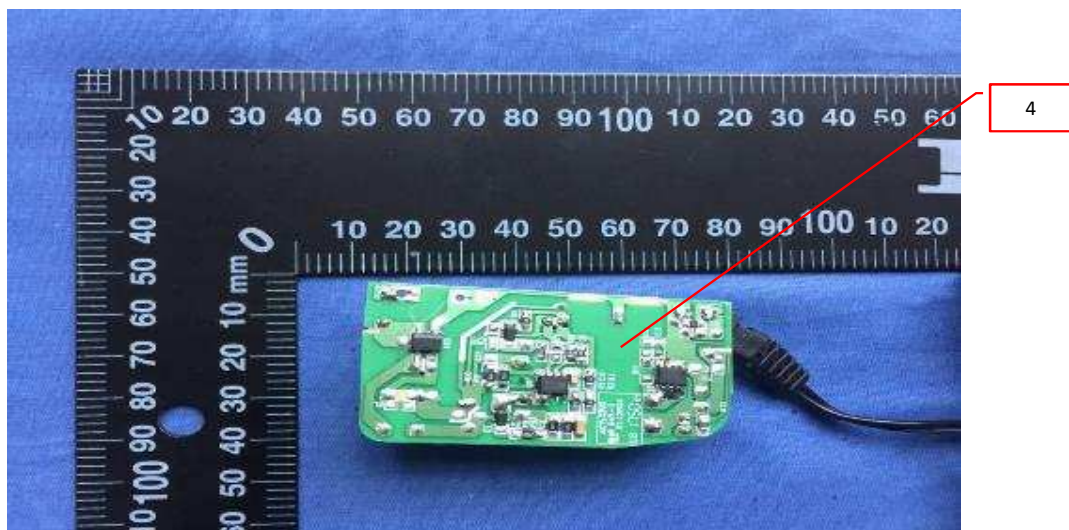


Photo 18: Internal view of EUT (GTM86100-1005-W2)



3.0 Product Photographs

Photo 19: External view of transformer

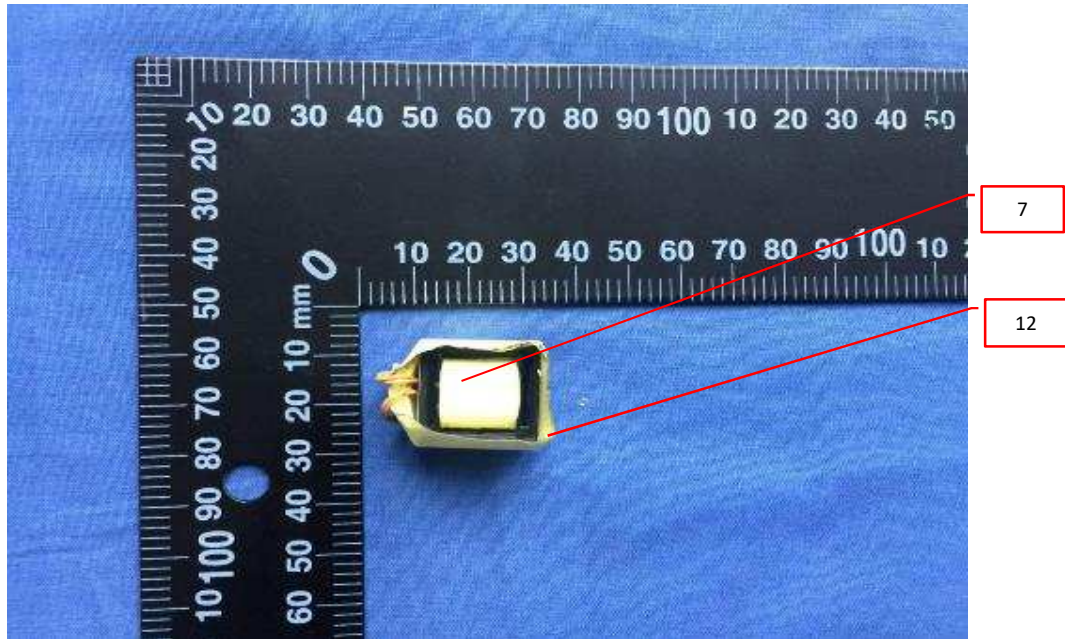
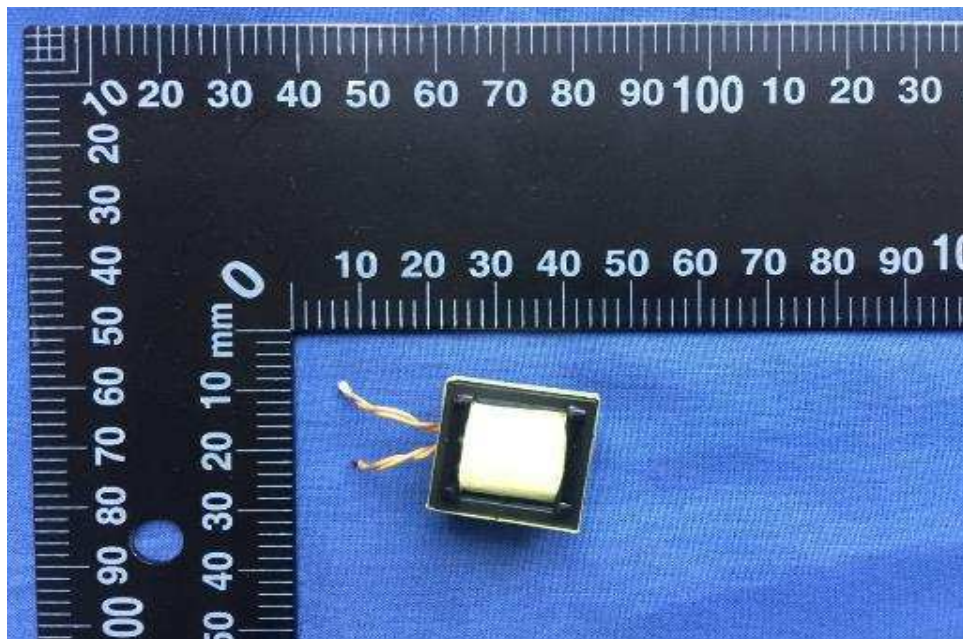


Photo 20: Transformer



3.0 Product Photographs

Photo 21: Transformer

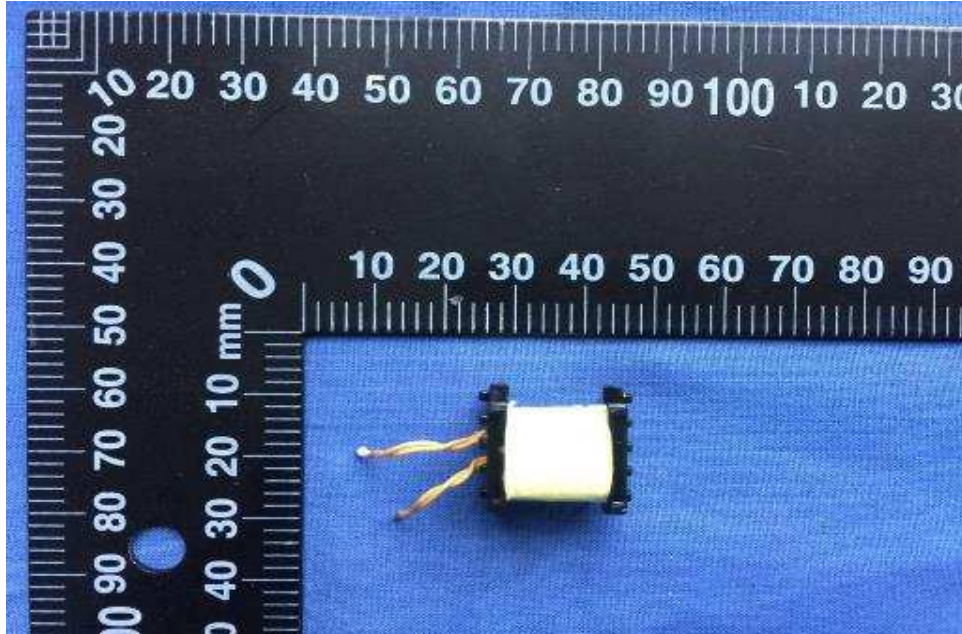
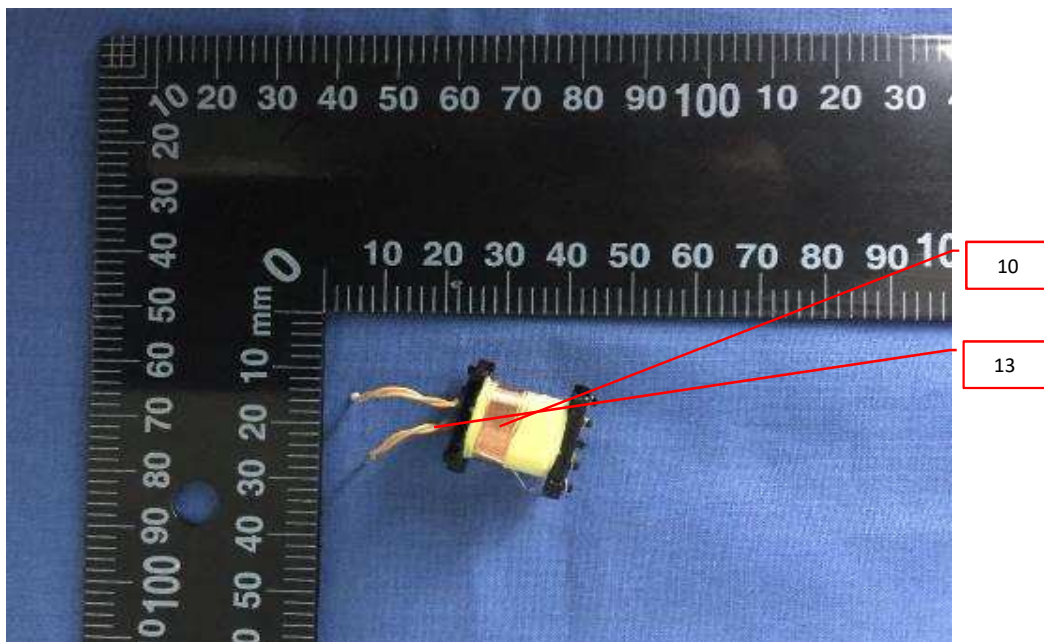


Photo 22: Transformer



3.0 Product Photographs

Photo 23: Secondary winding view of mains transformer (TIW)

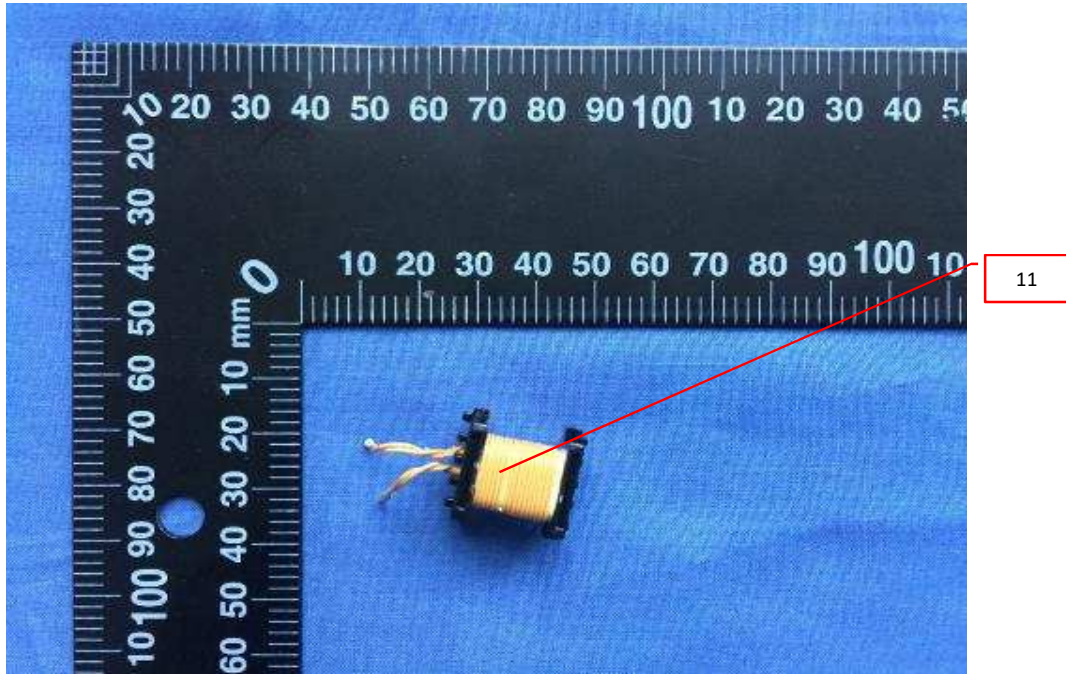
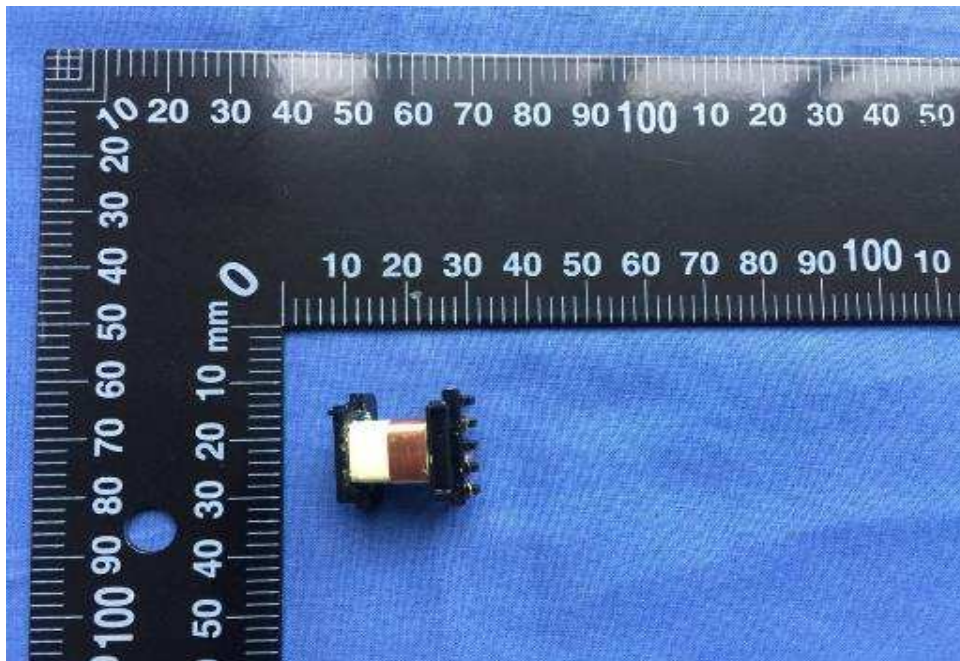


Photo 24: Transformer



3.0 Product Photographs

Photo 25: Primary winding view of mains transformer

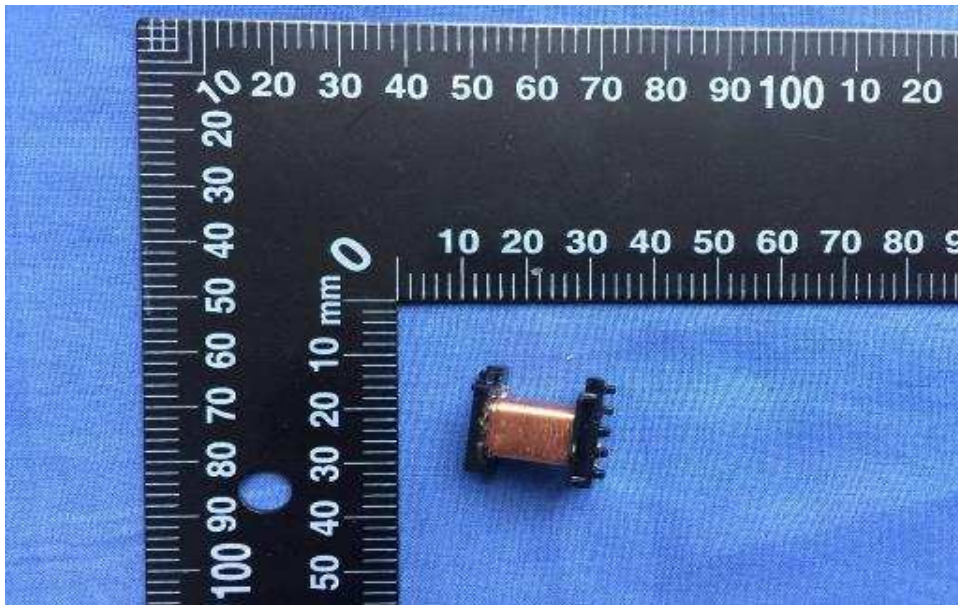
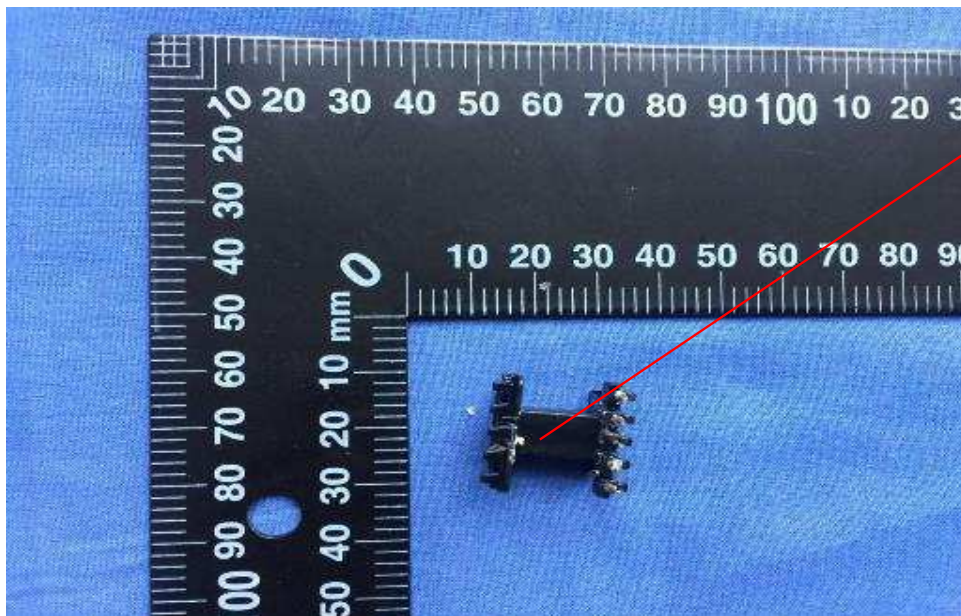


Photo 26: Bobbin view of transformer



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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, 2, 14, 15	1	Enclosure	SABIC JAPAN L L C	SE1X	PPE+PS, Min. V-1, Min. thickness: 1.5mm, 105°C	cURus
			SABIC JAPAN L L C	SE100	PPHOX, Min. V-1, Min. thickness: 1.5mm, 80°C	
			SABIC JAPAN L L C	940	PC, Min. V-0, Min. thickness: 1.5mm, 120°C	
			SABIC JAPAN L L C	CX7211	PC/ABS, Min. V-1, Min. thickness: 1.5mm, 90°C	
			SABIC JAPAN L L C	C2950	PC, Min. V-0, Min. thickness: 1.5mm, 115°C	
			SABIC JAPAN L L C	925U	Min. V-0 at 1.5 mm thickness 70°C	
			SABIC JAPAN L L C	945	PC, Min. V-0, Min. thickness: 1.5mm, 115°C	
			SABIC JAPAN L L C	CH6410	PC, Min. V-0, Min. thickness: 1.5mm, 120°C	
			SABIC JAPAN L L C	EXCY0098	PC/ABS, V-0, Min. thickness: 1.5mm, 100°C	
			ASAHI KASEI CORPORATION	540V	m-PPE, V-1, Min. thickness: 1.5mm, 100°C	
			COVESTRO DEUTSCHLAND AG [PC RESINS]	FR6005	PC, Min. V-0, Min. thickness: 1.5mm, 105°C	
			COVESTRO DEUTSCHLAND AG [PC RESINS]	6485	PC, Min. V-0, Min. thickness: 1.5mm, 115°C	
			IDEMITSU KOSAN CO LTD	AZ2201	PC, Min. V-0, Min. thickness: 1.5mm, 125°C	
2	2	Plug	GlobTek	US	15A, 125VAC (NEMA 1-15P) Intertek report No. : 171001667SHA-001	NR
2	3	Plug holder	SABIC Japan L L C	SE1X	PPE+PS, Min. V-1, Min. thickness: 1.5mm, 105°C	cURus
			SABIC JAPAN L L C	945	PC, Min. V-0, Min. thickness: 1.5mm, 120°C	
			NAN YA PLASTICS CORP PLASTICS 3RD DIV	6410G5	PA66, V-0, 130°C	

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Photo #	Item no. ¹	Name	Manufacturer/ trademark ²	Type / model ²	Technical data and securement means	Mark(s) of conformity ³
			Shenzhen Wuzhu Tech Co Ltd	WZ-4	Min. V-0, 130°C	
			WALEX ELECTRONIC(WUXI)CO LTD	T2	Min. V-0, 130°C	
				T2A		
				T2B		
				T4		
			DONGGUAN HE TONG ELECTRONICS	CEM1	Min. V-0, 130°C	
				2V0		
				FR4		
			Huizhou Shunjia Electronics Co Ltd	SJ-B	Min. V-0, 130°C	
			Cheerful Electronics(HK)Ltd	02	Min. V-0, 130°C	
				03		
				03A		
			Dongguan Daysun Electronic Co Ltd	DS2	Min. V-0, 130°C	
			Suzhou City Yilihua Electronics Co Ltd	YLH-1	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
4, 5, 17, 18	4	PCB	DAFENG AREX ELECTRONICS TECHNOLOGY CO LTD	02V0	Min. V-0, 130°C	cURus
				04V0		
				03V0		
			BRITE PLUS ELECTRONICS(S UZHOU)CO LTD	DKV0-3A	Min.V-0, 130°C	
				DGV0-3A		
			KUOTIANG ENT LTD	C-2	Min.V-0, 130°C	
				C-2A		
			SHENZHEN TONGCHUANXIN ELECTRONICS CO LTD	tcx	Min. 1,6 mm thickness, min. V-0, 130°C	
			PACIFIC WIN INDUSTRIAL LTD	PW-02	Min.V-0, 130°C	
				PW-03		
			YUANMAN PRINTED CIRCUIT CO LTD	1V0	Min.V-0, 130°C	
			SUZHOU XINKE ELECTRONICS CO LTD	XK-2	Min.V-0, 130°C	
				XK-3		
			KUNSHAN CITY HUA SHENG CIRCUIT BOARD CO LTD	HS-S	Min.V-0, 130°C	
			JIANGSU DIFEIDA ELECTRONICS CO LTD	DFD-1	Min.V-0, 130°C	
			SHANGHAI H-FAST ELECTRONIC CO LTD	211001	Min.V-0, 130°C	
				411001		
			Various	Various	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
4	5	Current fuse	LITTELFUSE WICKMANN WERKE	392	T1A or 2A, 250V sub-miniature fuse (F1)	cURus
			Ever Island Electric Co., Ltd. and Walter Electric	2010 series	T1A or 2A, 250V sub-miniature fuse (F1)	
			Shenzhen Lanson Electronics Co. Ltd.	SMT	T1A or 2A, 250V sub-miniature fuse (F1)	
			Conquer Electronics Co., Ltd.	MST	T1A or 2A, 250V sub-miniature fuse (F1)	
			Cooper Bussmann LLC	SS-5	T1A or 2A, 250V sub-miniature fuse (F1)	
			Bel Fuse Ltd.	RST-Serie(s)	T1A or 2A, 250V sub-miniature fuse (F1)	
			SMART ELECTRONICS INC	SPT	T1A or 2A, 250V sub-miniature fuse (F1)	
			SUNNY EAST ENTERPRISE CO LTD	TSP series	T1A or 2A, 250V sub-miniature fuse (F1)	
			Conquer Electronics Co., Ltd.	PTU	T1A or 2A, 250V sub-miniature fuse (F1)	
			Littelfuse Inc	877	T1A or 2A, 250V sub-miniature fuse	
			NIPPON SEISEN CABLE LTD	SLT	T1A or 2A, 250V sub-miniature fuse (F1)	
			Walter Electronic Co. Ltd.	ICP	T1A or 2A, 250V sub-miniature fuse (F1)	
			XC ELECTRONICS (SHENZHEN) CORP LTD	5TE	T1A or 2A, 250V sub-miniature fuse (F1)	

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
			XC ELECTRONICS (SHENZHEN) CORP LTD	4T series	T1A or 2A, 250V sub-miniature fuse (F1)	
4, 17	6	Y-Capacitor	TDK-EPC Corporation, Capacitors Group Circuit Devices Business Group	CD	Y1, AC250V, max 2200pF, 25/085/21/B (CY1, CY2) (optional)	cURus
			Murata Mfg. Co., Ltd.	KX	Y1, AC250V, max 2200pF, 25/125/21/B (CY1, CY2) (optional)	
			SUCCESS ELECTRONICS CO LTD	SE	Y1, AC250V, max 2200pF, 30/125/56/C (CY1, CY2) (optional)	
			SUCCESS ELECTRONICS CO LTD	SB	Y1, AC250V, max 2200pF, 30/125/56/C (CY1, CY2) (optional)	
			JYA-NAY CO LTD	JN	Y1, AC250V, max 2200pF, 30/125/56/C (CY1, CY2) (optional)	
			WELSON INDUSTRIAL CO LT D	WD	Y1, AC250V, max 2200pF, 30/125/56/C (CY1, CY2) (optional)	
			SAMWHA CAPACITOR CO LTD	SD	Y1, AC250V, max 2200pF, 30/125/56/C (CY1, CY2) (optional)	
			NAN JING YUYUE ELECTRONICS CO LTD	CT7	Y1, AC250V, max 2200pF, 30/125/56/C (CY1, CY2) (optional)	
			YINAN DON'S ELECTRONIC COMPONENT CO LTD	CT81	Y1, AC250V, max 2200pF, 30/125/56/C (CY1, CY2) (optional)	
			JYH CHUNG ELECTRONICS CO LTD	JD	Y1, AC250V, max 2200pF, 30/125/56/C (CY1, CY2) (optional)	
			JYH CHUNG ELECTRONICS CO LTD.	JY	Y1, AC250V, max 2200pF, 30/125/56/C (CY1, CY2) (optional)	
			Various	Various	Y1, AC250V, max 2200pF, 30/125/56/C (CY1, CY2) (optional)	

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
4, 6, 17, 19	7	Transformer	GlobTek	90E10PFX0	Class B Input: 100 to 240Vac, 10W; Output: 5 to 5.2V Details see illustration No(s). 1	NR
				90E10PF02		
			Dee Van	90E10PFX0		
				90E10PF02		
			BOAM	90E10PFX0		
				90E10PF02		
	8	Insulation system (not shown)	Haopuwei	90E10PFX0	Class B	cURus
				90E10PF02		
			Globtek	GTX-130-TM		
				GTX-130-TM		
			Haopuwei	ZT-130		
			BOAM	BOAM-01		
13, 26	9	Bobbin		B01	V-0, 150°C, thickness 0.45 mm min.	cURus
			Dee Van	YCI-130		
			HITACHI CHEMICAL CO LTD	CP-J-8800		
			SUMITOMO BAKELITE CO LTD	PM-9820		
			SUMITOMO BAKELITE CO LTD	PM-9630		
			CHANG CHUN PLASTICS CO LTD	T375J		
			CHANG CHUN PLASTICS CO LTD	T373J		
			CHANG CHUN PLASTICS CO LTD	T375HF		

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
9, 22	10	Magnet wire	HUIZHOU GOLDEN OCEAN MAGNET WIRE FACTORY	UEW-X	130°C	cURus
			SHENZHEN DAYANG INDUSTRY CO LTD	UEW		
			WA TAI ELECTROTECHNICAL MATERIALS FACTORY LTD	UEW		
			FENG CHING METAL CORP	UEW		
			TAI-I COPPER (GUANZHOU) CO LTD	UEW		
10, 23	11	Triple-insulated wire	Furukawa Electric Co., Ltd.	TEX-E	Class B, reinforced insulation (Secondary)	cURus
			SUZHOU YUSHENG ELECTRONIC CO LTD	TIW-B		
				TWE-3		
			DAH JIN TECHNOLOGY CO LTD	TLW-B		
			Furukawa Electric Co., Ltd.	TEX-E		
			COSMOLINK CO. Ltd.	TIW-M		
			YOUNG CHANG SILICONE CO LTD	STW-B		
			Great Leoflon Industrial Co., Ltd.	TRW (B) Serie(s)		
			E&B TECHNOLOGY CO LTD	E&B-B-X.XX		
			DONGGUAN KOSHEN INSULATOR CO LTD	TIW-B		

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Photo #	Item no. ¹	Name	Manufacturer/ trademark ²	Type / model ²	Technical data and securement means	Mark(s) of conformity ³
8, 19	12	Insulating tape	SYMBIO INC	35660	Min.130°C	cURus
				35661		
				35660Y		
			3M COMPANY ELECTRICAL MARKETS DIV (EMD)	1350F-1		
				1350T-1		
			BONDTEC PACIFIC CO LTD	370S		
			JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CO LTD	PZ		
				CT		
				WF		
			JINGJIANG JINGYI ADHESIVE PRODUCT CO LTD	JY25-A		
CHANG SHU LIANG YI TAPE INDUSTRY CO LTD	LY-XX					
10, 22	13	PTFE tubing	GREAT HOLDING INDUSTRIAL CO LTD	TFT	Min. 300V, 200°C	cURus
				TFS		
			SHENZHEN WOER HEAT- SHRINKABLE MATERIAL CO LTD	WF	600V, 200°C	
			CHANGYUAN ELECTRONICS (SHENZHEN) CO LTD	CB-TT-T	Min. 300V, 200°C	
				CB-TT-S		
			ZEUS	TFE-TW-300	Min.150V, 200°C	
				TFE-SW-600		

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Photo #	Item no. ¹	Name	Manufacturer/ trademark ²	Type / model ²	Technical data and securement means	Mark(s) of conformity ³
			CENTRA SCIENCE CORP	CNR-10D431-561K	Min. 300Vac, min. 385Vdc, fulfilled 6kV/3kA pulse test. MOV1 (Optional)(For Model: GT*86100-**-W2* only)	
			CENTRA SCIENCE CORP	CNR-14D431-561K		
			Uppermost Electronic Industries Co Ltd	V10K300		
				V10K320		
				V10K350		
				V10K385		
				V14K300		
				V14K320		
				V14K350		
				V14K385		
			Jya-Nay Co Ltd	10D431-561K		
				14D431-4561K		
			Joyin Co Ltd	JVR10N431-56		
				JVR14N431-561K		
			Panasonic Corporation	10DK431-561U		
				14DK431-561U		
			Thinking Electronic	TVR10431-561		
				TVR14431-561		
			Guangdong Fenghua Advanced Technology Holding Co Ltd. Xianhua New Sensitive Components Branch	FNR-10K431-561		
				FNR-14K431-561		

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
4	14	Varistor	Brightking (Shenzhen)Co Ltd	10D431-561K		cURus
				14D431-561K		
			Littelfuse Inc	V300-		
				V385LA10P		
				V385LA20AP		
				V10E300P-385P		
				V14E300P-385P		
			Guangxi New Future Information Industry Co Ltd	10D431-561K		
				14D431-561K		
			Walsin Technology Corp	VZ10D456K		
				VZ14D456K		
			Success Electronics Co Ltd	SVR10D431K~561K		
				SVR14D431K~561K		
			Shantou Hongzhi Electronics Ltd	10D471K	Min310Vac, Min510Vdc MOV1 (Optional)(For Model: GT*86100-**-W2* only)	
			BestBright Electronics Co.,Ltd.		Min300Vac, Min470Vdc MOV1 (Optional)(For Model: GT*86100-**-W2* only)	
			CeNtRa Science(Holdings) Ltd		Min300Vac, Min470Vdc MOV1 (Optional)(For Model: GT*86100-**-W2* only)	
			Huizhou Songlong Xindian Electronic Technology Co.,LTD		Min300Vac, Min470Vdc MOV1 (Optional)(For Model: GT*86100-**-W2* only)	

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
17	15	Resistor Fuse	Anhui Changsheng Electronics Co., Ltd	RXF21-2W	3.3ohm,2W (RT1)	cURus
			Shenzhen Great Electronics Co. Ltd.	RXF		
			Shenzhen Kayocota Electronics Co., Ltd	FRKNP		
			Jiang Su Xin Yang Electronic Element Co.,Ltd	RF10		
			TZAI YUAN Enterprise Co., Ltd	KNF		
			ChienTung Electronics Co.,Ltd	FKN		
			HuaSheng Electronics Co.,Ltd	FKN		
			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

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 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.
5. Grounding - This product is not provided with a means of grounding as it is double insulated for Class II model.
6. Polarized Connection - This product is provided with a polarized power supply connection.
7. Internal Wiring - no primary internal wiring.
8. Schematics - Refer to Illustration No(s). 3-4 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. 5 for details.
10. Cautionary Markings - Refer to illustrations No. 5 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.
12. Transformer - Supplier records must be provided that indicate the received shipment of transformers (section 4.0, item 7) was constructed as indicated in Illustrations 1. These records must be available at the factory for inspection on every received shipment.

7.0 Illustrations

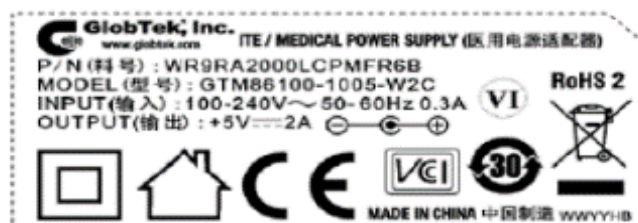
Illustration 5 - Marking label

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

For USB output:





For DC cord output:



Conforms to AAMI STD. ES 60601-1, IEC 60601-1-11
Certified to CAN/CSA STD.C22.2 NO.60601-1

8.0 Test Summary					
Evaluation Period	12/30/2017-3/1/2018		Project No.	171201811SHA	
Sample Rec. Date	30-Dec-2017	Condition	Prototype	Sample ID.	0171230-36-001
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 [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			
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			

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)	

8.1 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:	Fitzgerald Zhang	Reviewed by:	Justin Yu
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
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 and/or revisions.

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. Angela Han

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>
All the product covered by this report Between mains part and secondary circuits	4000Vac	1 s
<u>Product - One sample from each shipment of Section 4.0 item 7:</u>	<u>Test Voltage</u>	<u>Test Time</u>
Between prim. and sec. output	3000Vac	1min
Between prim. and core	3000Vac	1min

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

[illegible]