1.0 Reference and Address					
Report Number	140900435SHA-001	Original Issued:	10-Nov-2014	Revised:	19-Feb-2021
Standard(s)	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 (R2018) [CSA C22.2#60601-1:2014 Ed.3]				

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	(201)784-1000 Ext.253	Phone	86 512 6279 0301 Ext.189
FAX	(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	Product covered by this report is medical power supply module, which can be used as a part of medical equipment. The installation and use for the insulation construction shall be finally determined in the end product. All the types are designed for continuous operation and no applied part is defined. The product is designed to be operated at max. 5000m above sea level. The insulation between primary and secondary circuits of EUT is evaluated as 2MOPP in this report as customer's request.
Models	GT followed by M, - or H; followed by 43007-; followed by A, B or C; followed by 01 to 60; followed by 05, 07, 09, 12, 15, 18, 24, 36 or 48; may be followered by -0.1 to -11.9; followed by -F or -FW.
Model Similarity	GT*43007-***** The 1st "*" can be 'M' or '-'or 'H' for market identification and not related to safety. The 2nd "*" is A, B, or C and is related to PCB size: A= 2"x3", B=2"x4", C=3"x5". The different PCB sizes are only for installation purpose in end product with no safety spacing modification. The 3rd "*" denote the rated output wattage designation, which can be "01" to "60", with interval of 1. The 4th "*" denote the standard rated output voltage designation, which can be "05", "07", "09", "12", "15", "18", "24", "36" or "48". Each standard rated output voltage designation corresponds to a transformer model. Each transformer model is identical in insulation construction including clearance and creepage except number of turns per coil. The 5th "*" is optional deviation, subtracted from standard output voltage, which can be "-0.1" to "-11.9" with interval of 0.1, or blank to indicate no voltage different. The 4th and 5th asterisks together denote the output voltage with a range of 5-48 volts. The 6th "*" can be "-F" or "-FW". "-F" represents Class I model and "-FW" represents Class II model. Due to the diffrerent power comsuption, the sizes of heat sink may be two alternative types.
Ratings	Input: 100-240V~, 50-60Hz or 50/60Hz, 1.5A; Output: Refer to illustration No.1 for details.
Other Ratings	NA
Conditions of Acceptability	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. 1. Scope of Power Supply evaluation defers the following clauses to be determined as part of the end product investigation: • 60601-1 Clause 7.5 (Safety Signs), • 60601-1 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.), • 60601-1 Clause 8.11.5 (Mains Fuse with High Breaking Capacity), • 60601-1 Clause 9 (ME Hazard), except 9.1 and 9.3 are evaluated, • 60601-1 Clause 10 (Radiation), • 60601-1 Clause 11.7 (Biocompatibility), • 60601-1 Clause 14 (PEMS), • 60601-1 Clause 15 (Construction), • 60601-1 Clause 16 (ME Systems), • 60601-1 Clause 17 (EMC).

2.0 Product Description	
	2. Open frame model • Suitability of the enclosure should be evaluated when installed in the end product including access to energized parts, clearance & creepage distance measurement and mechanical strength. • Temperature Testing should be performed on this component when installed in the end product.

3.0 Product Photographs

Photo 1 - Component side view of board with small size heatsink

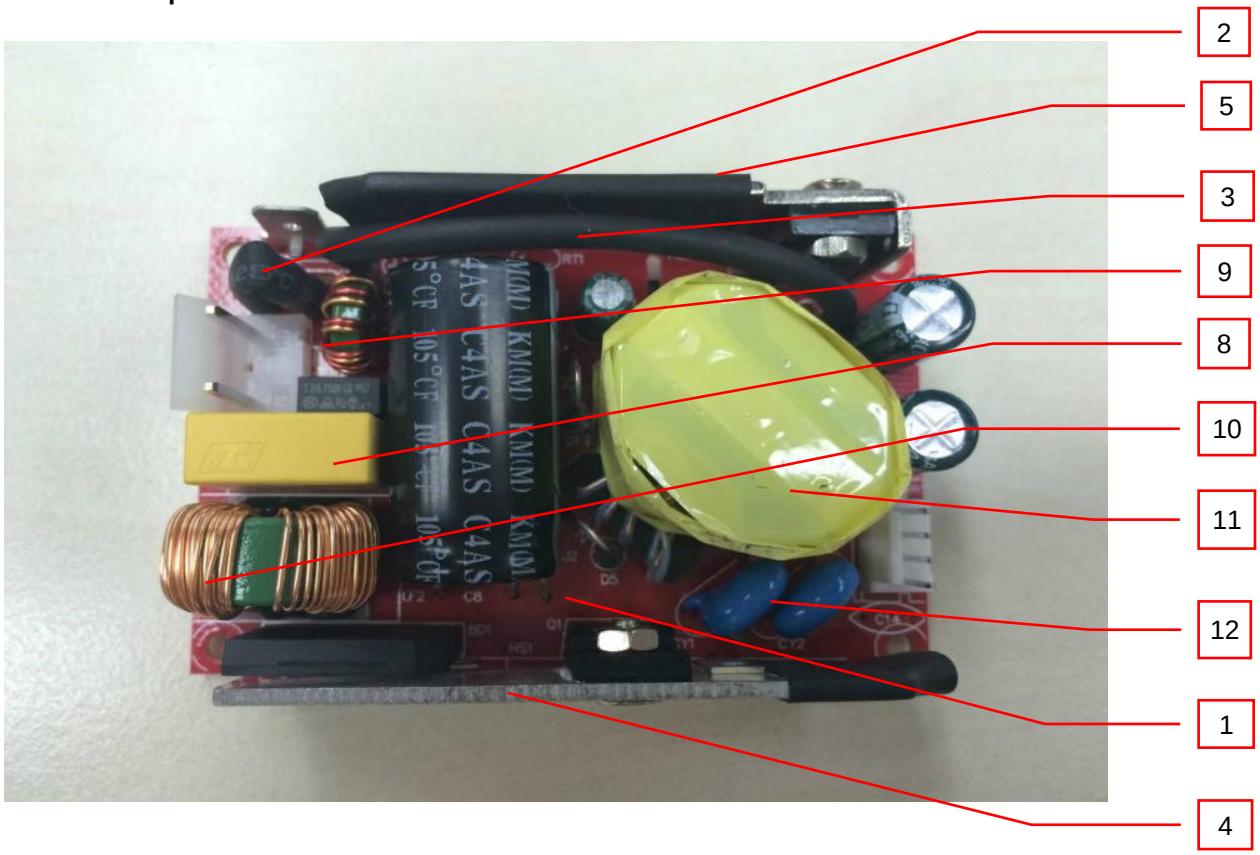
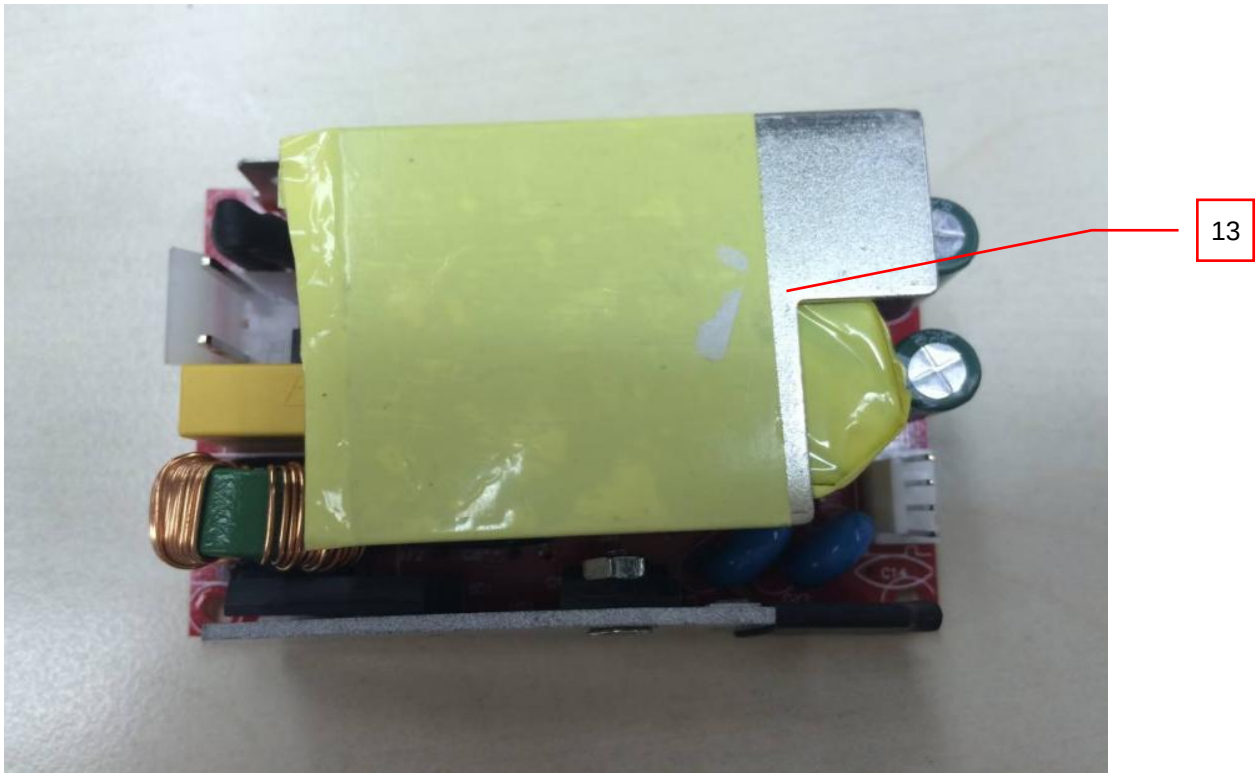


Photo 2 - Component side view of board with large size heatsink



3.0 Product Photographs

Photo 3 - Soldering side view of board

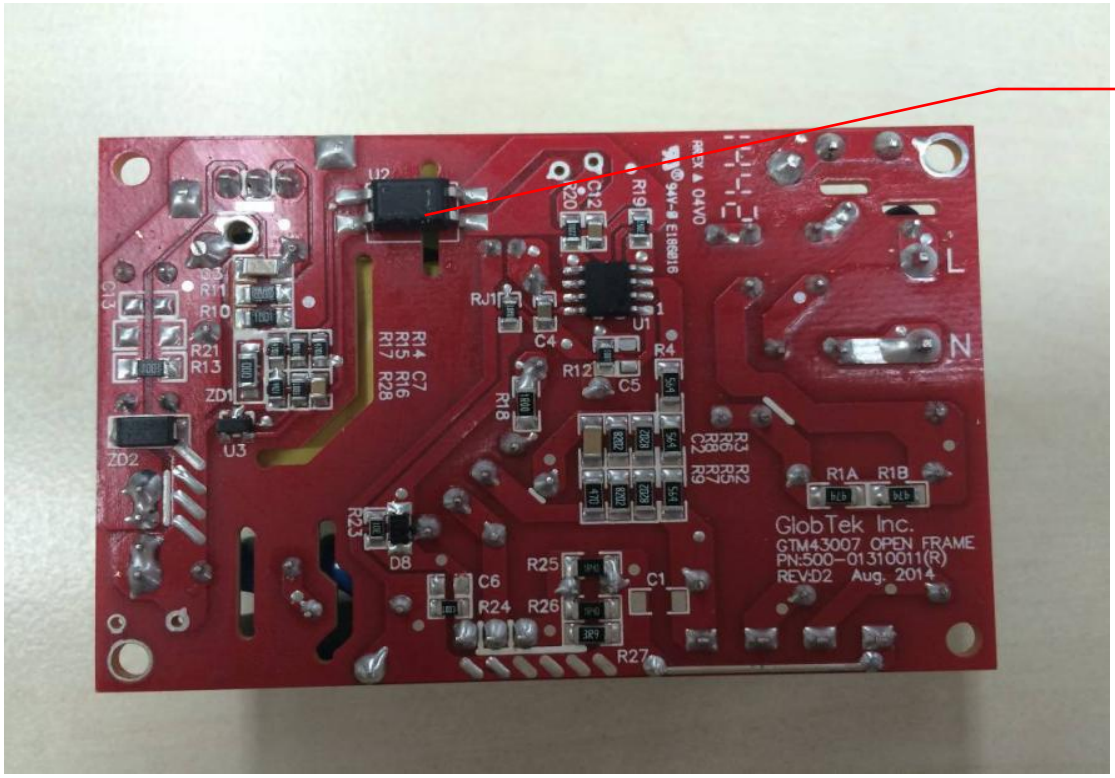
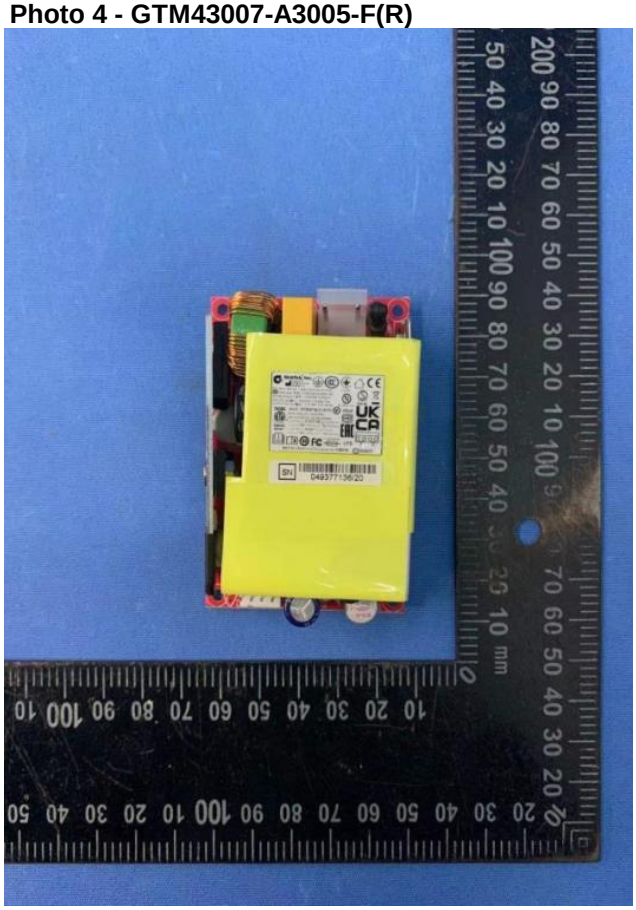


Photo 4 - GTM43007-A3005-F(R)



3.0 Product Photographs

Photo 5 - GTM43007-A3005-F(R)

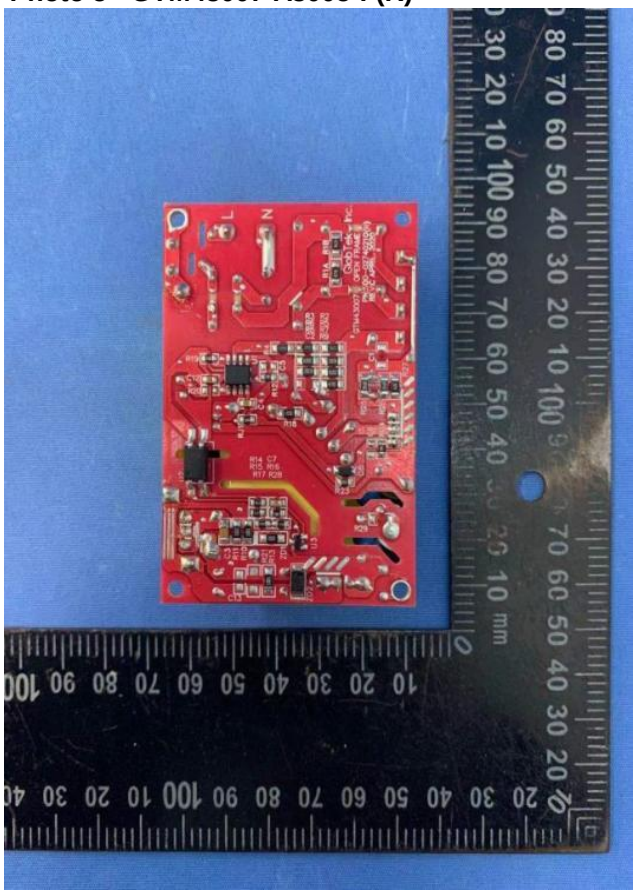
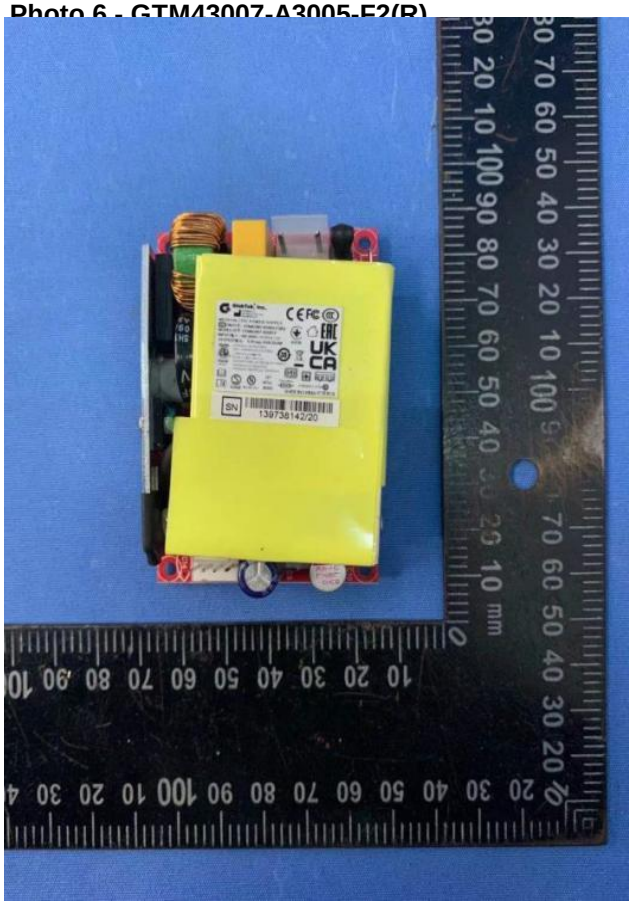


Photo 6 - GTM43007-A3005-F2(R)



3.0 Product Photographs

Photo 7 - GTM43007-A3005-F2(R)

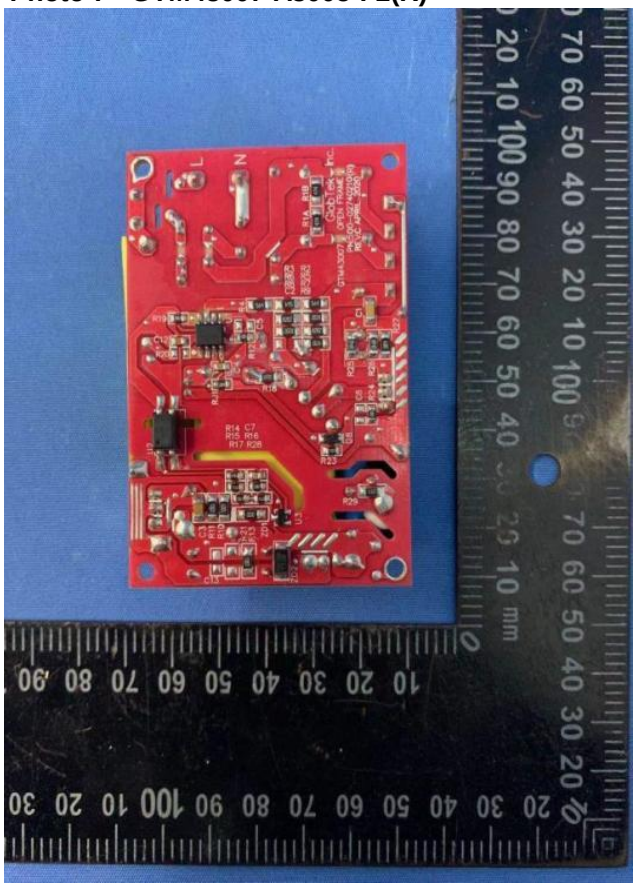
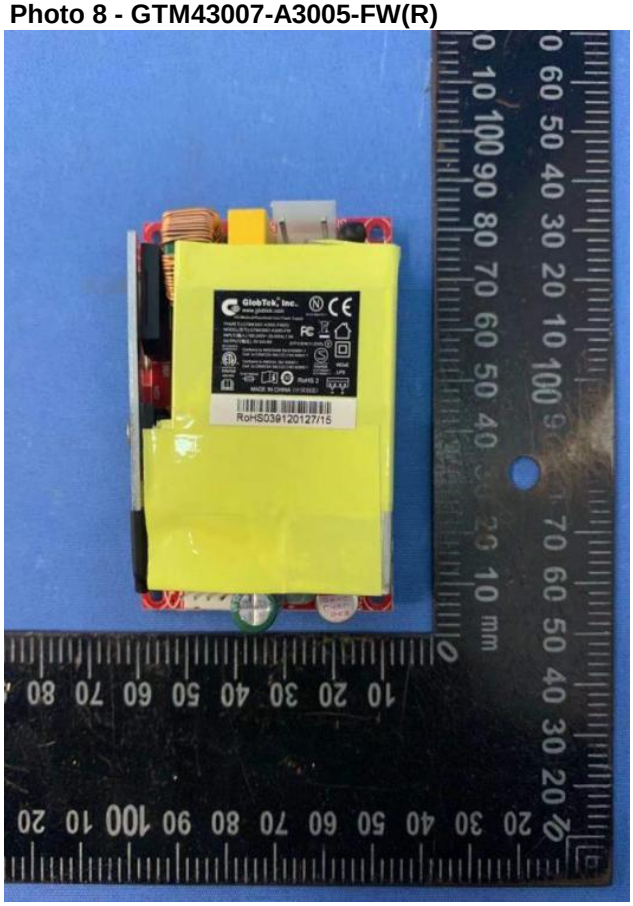


Photo 8 - GTM43007-A3005-FW(R)



3.0 Product Photographs

Photo 9 - GTM43007-A3005-FW(R)

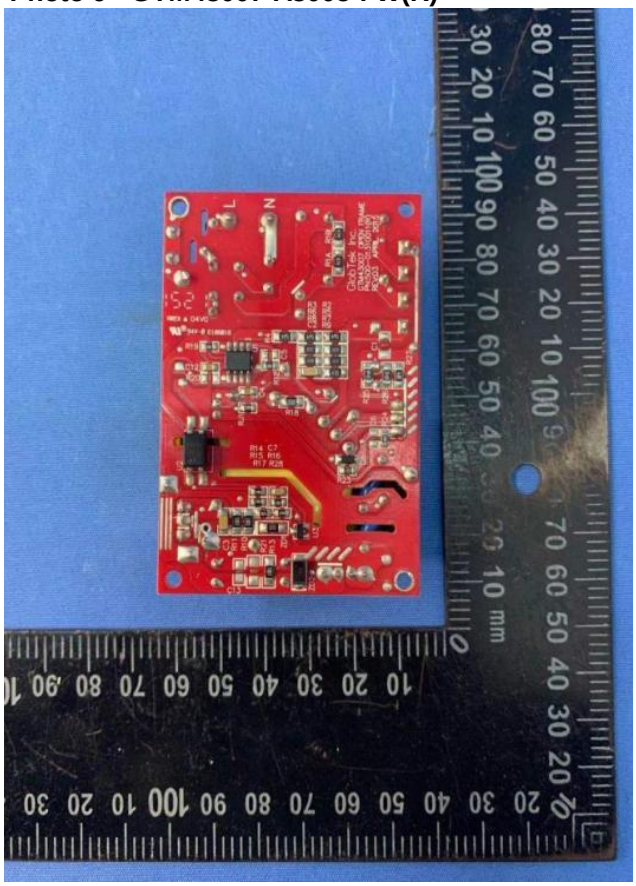
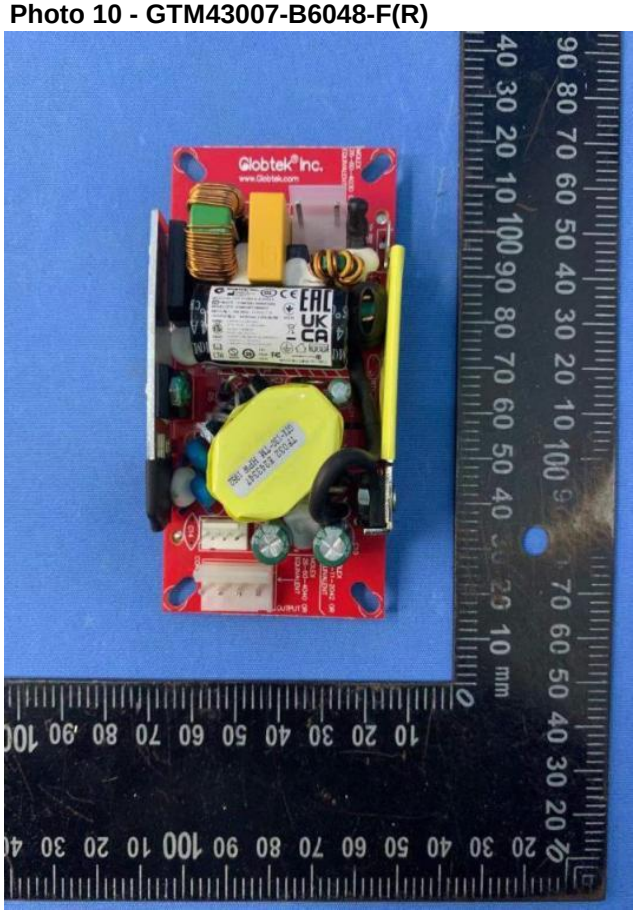


Photo 10 - GTM43007-B6048-F(R)



3.0 Product Photographs

Photo 11 - GTM43007-B6048-F(R)

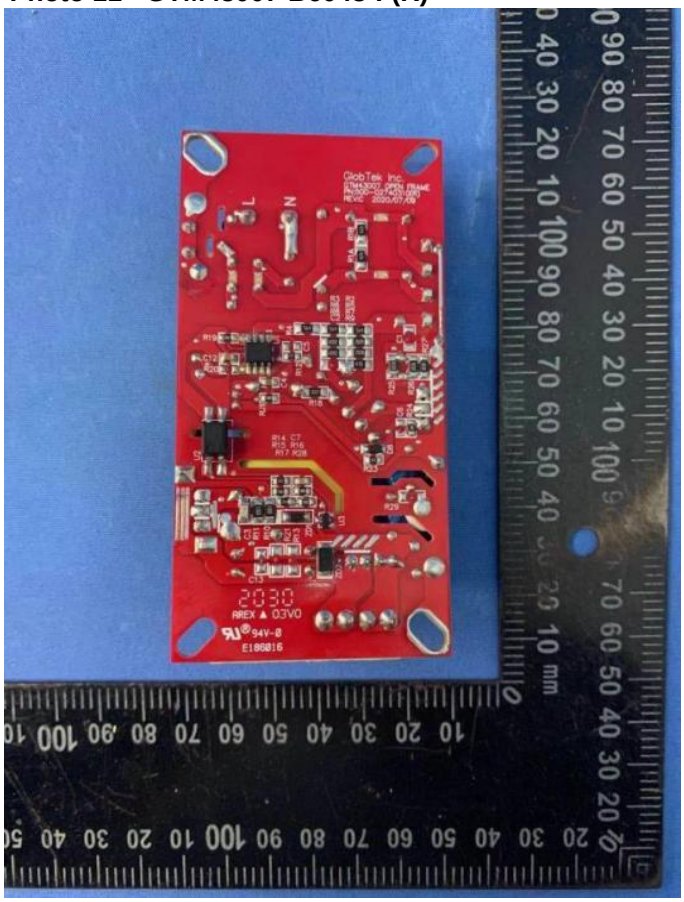
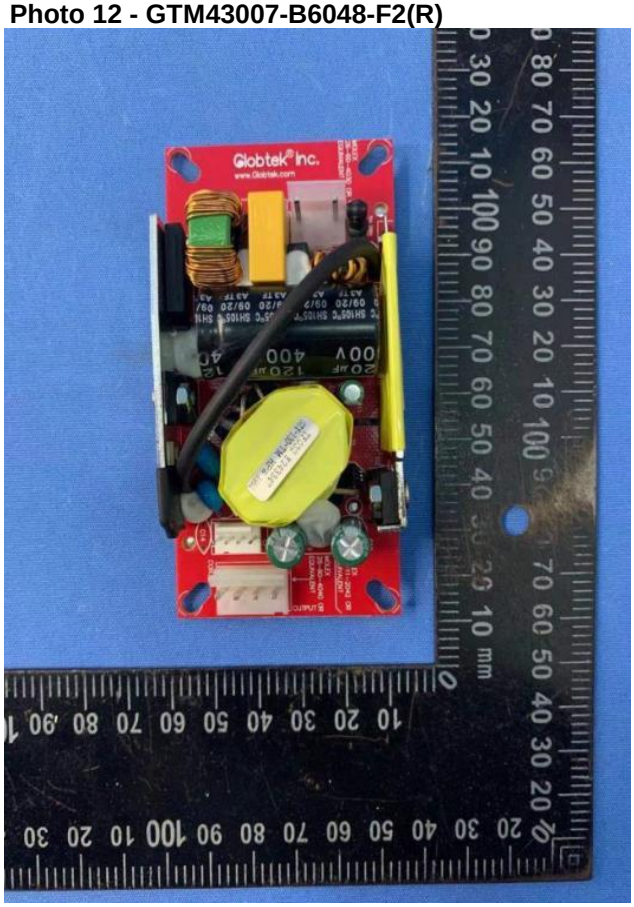


Photo 12 - GTM43007-B6048-F2(R)



3.0 Product Photographs

Photo 13 - GTM43007-B6048-F2(R)

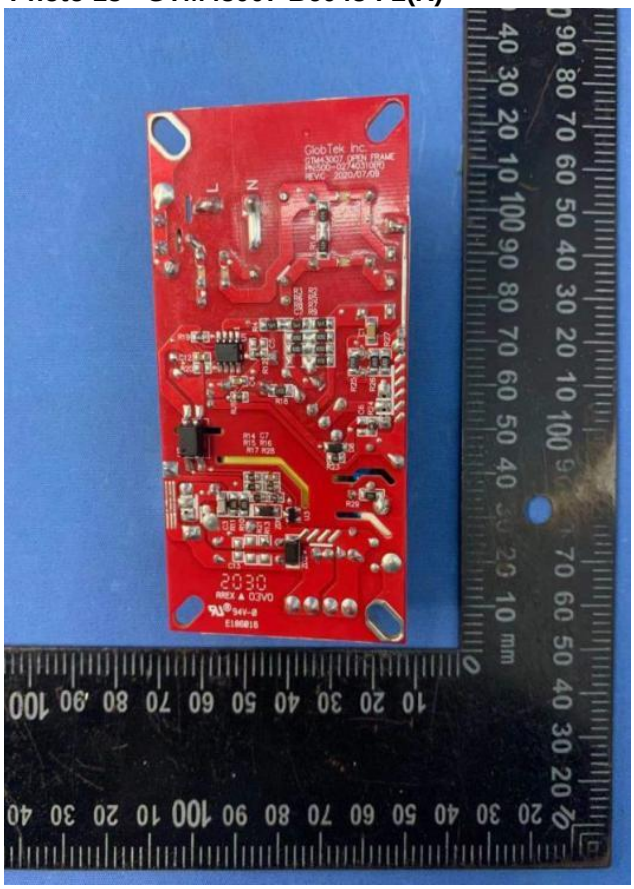
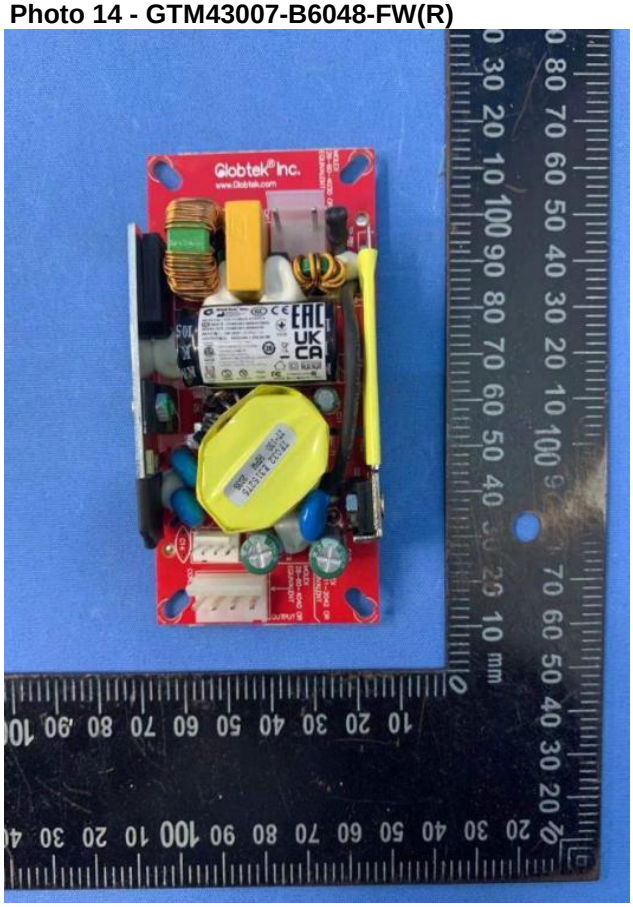


Photo 14 - GTM43007-B6048-FW(R)



3.0 Product Photographs

Photo 15 - GTM43007-B6048-FW(R)

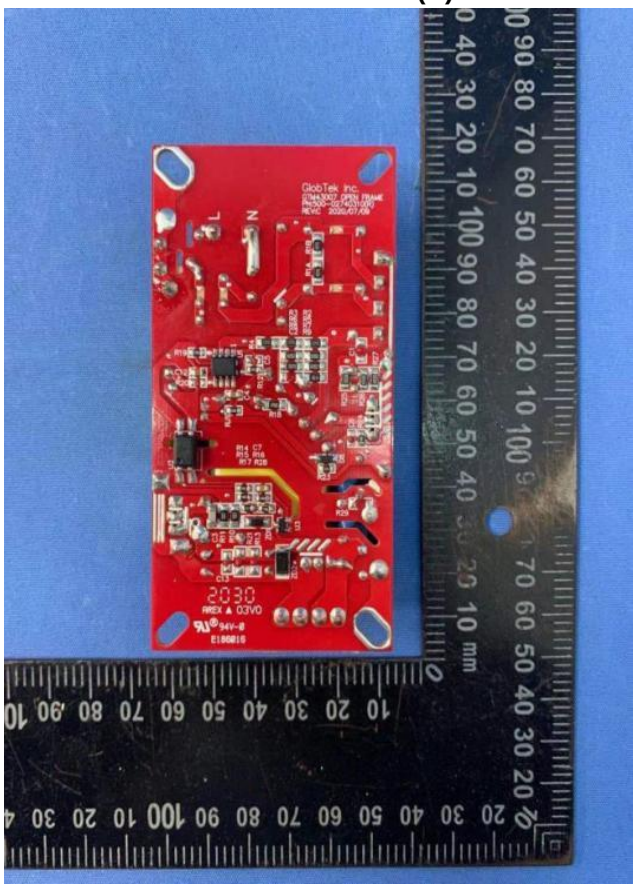
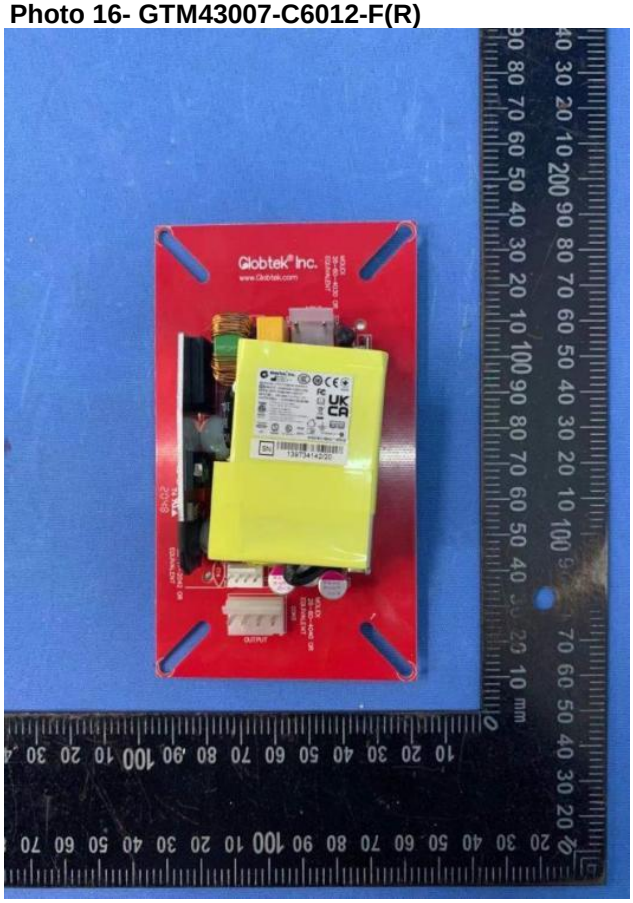


Photo 16- GTM43007-C6012-F(R)



3.0 Product Photographs

Photo 17- GTM43007-C6012-F(R)

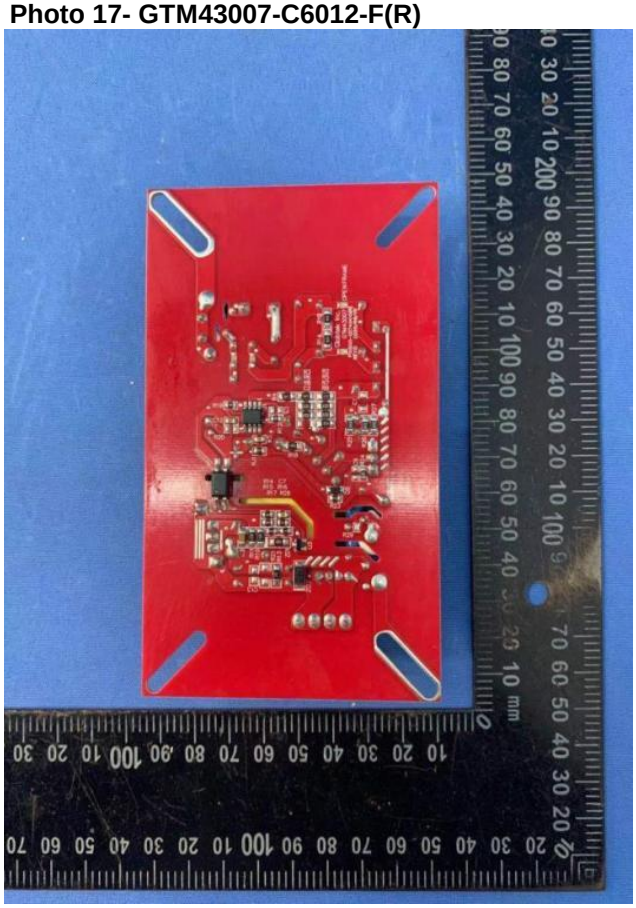


Photo 18 - GTM43007-C6012-F2(R)

3.0 Product Photographs

Photo 19 - GTM43007-C6012-F2(R)

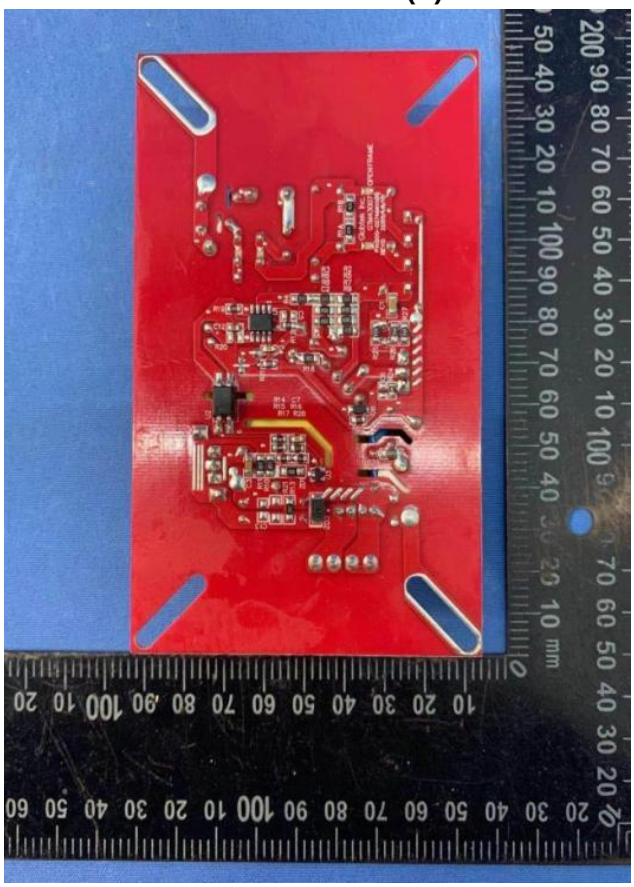
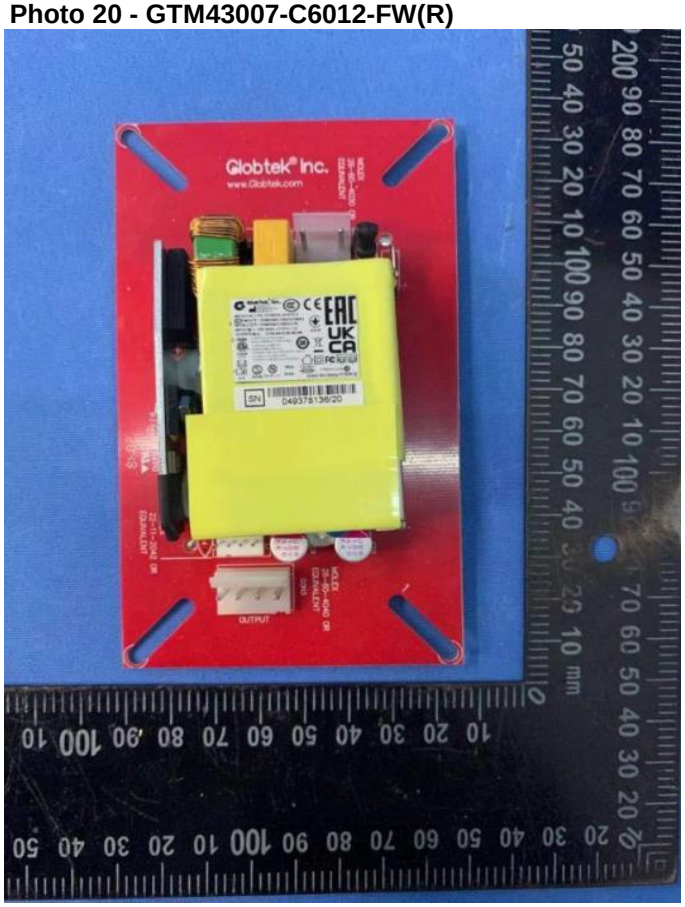
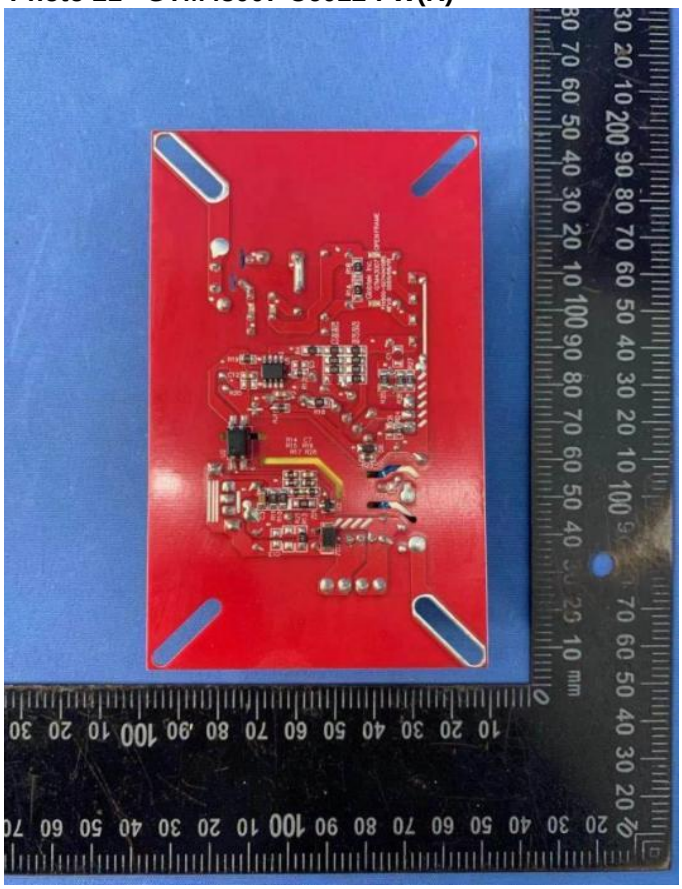


Photo 20 - GTM43007-C6012-FW(R)



3.0 Product Photographs

Photo 21 - GTM43007-C6012-FW(R)



4.0 Critical Components

Photo #	Item no.[1]	Name	Manufacturer/ trademark[2]	SALIPT S-901-600	Technical data and securement means	Mark(s) of conformity [3]
1	1	PCB material	PACIFIC WIN INDUSTRIAL LTD	PW-02	Min. V-0, min 1.6 mm thickness, 130°C	cURus
				PW-03		
			YILIHUA	YLH-1		
				YLH-2		
			AREX	02V0		
				03V0		
				04V0		
			BRITE PLUS ELECTRONICS (SUZHOU) CO LTD	DKV0-3A		
				DGV0-3A		
			SHENZHEN TONGCHUANGXIN ELECTRONICS CO LTD	TCX		
			WALEX ELECTRONIC (WUXI) CO LTD	T2		
				T2A		
				T2B		
				T4		
			DONGGUAN HE TONG ELECTRONICS CO LTD	CEM1		
				2V0		
				FR4		
			CHEERFUL ELECTRONIC (HK) LTD	02		
				03		
				03A		
			DONGGUAN DAYSUN ELECTRONIC CO LTD	DS2		
			KUOTIANG ENT LTD	C-2		
				C-2A		
			YUANMAN PRINTED CIRCUIT CO LTD	1V0		
			SUZHOU XINKE ELECTRONICS CO LTD	XK-2		
				XK-3		
			KUNSHAN CITY HUA SHENG CIRCUIT BOARD CO LTD	HS-S		
			JIANGSU DIFEIDA ELECTRONICS CO LTD	DFD-1		
			HUIZHOU SHUNJIA ELECTRONICS CO LTD	SJ-B		
			SHANGHAI H-FAST ELECTRONIC CO LTD	211001		
				411001		
			Various	Various		

4.0 Critical Components						
Photo #	Item no.[1]	Name	Manufacturer/ trademark[2]	SALIPT S-901-600	Technical data and securement means	Mark(s) of conformity [3]
1	2	Fuse	CONQUER ELECTRONICS CO LTD	MST	T2A, 250V, Rated breaking capacity 50A (F1, F2) (F2 is optional.)	cURus
			EVER ISLAND ELECTRIC CO LTD & WALTER ELECTRIC	2010	T2A, 250V, Rated breaking capacity 130A (F1, F2) (F2 is optional.)	
			BEL FUSE INC	5ST	T2A, 250V, Rated breaking capacity 100A (F1, F2) (F2 is optional.)	
			COOPER BUSSMANN LLC	SS-5	T2A, 250V, Rated breaking capacity 35A (F1, F2) (F2 is optional.)	
			DAS & SONS INTERNATIONAL LTD	385T series	T2A, 250V, Rated breaking capacity 35A (F1, F2) (F2 is optional.)	
			WALTER ELECTRONIC CO LTD	ICP series	T2A, 250V, Rated breaking capacity 50A (F1, F2) (F2 is optional.)	
			SUN ELECTRIC CO	5T	T2A, 250V, Rated breaking capacity 100A (F1, F2) (F2 is optional.)	
			SHENZHEN LANSON ELECTRONICS CO LTD	SMT	T2A, 250V, Rated breaking capacity 35A (F1, F2) (F2 is optional.)	
			Bel Fuse Ltd.	RST	T2A, 250V, Rated breaking capacity 100A (F1, F2) (F2 is optional.)	
			Zhongshan Lanbao Electrical Appliances Co., Ltd.	RTI-10 series	T2A, 250V, Rated breaking capacity 50A (F1, F2) (F2 is optional.)	
			Dongguan Better Electronics Technology Co., Ltd.	932	T2A, 250V, Rated breaking capacity 100A (F1, F2) (F2 is optional.)	
			Hollyland Compoany Limited	5ET	T2A, 250V, Rated breaking capacity 63A (F1, F2) (F2 is optional.)	
			Sunny East Enterprise Co. Ltd.	CFD-Serie(s)	T2A, 250V, Rated breaking capacity 50A (F1, F2) (F2 is optional.)	
			Conquer Electronics Co., Ltd.	MET series	T2A, 250V, Rated breaking capacity 35A (F1, F2) (F2 is optional.)	
			KUNSHAN NEW ZHICHENG ELECTRONICS TECHNOLOGIES CO LTD	1007		
				1015		
			Suzhou Jiahuishu Electronic Co Ltd	1007		
				1015		

4.0 Critical Components						
Photo #	Item no.[1]	Name	Manufacturer/ trademark[2]	SALIPT S-901-600	Technical data and securement means	Mark(s) of conformity [3]
1	3	Earthing wire	ZHUANG SHAN CHUAN ELECTRICAL PRODUCTS (KUNSHAN) CO LTD	1007	Min. 18AWG, min. 300Vac, min. 80°C (for class I model)	cURus
				1015		
			GLOBTEK INC	1007		
				1015		
			Various	Various		
1	4	Heatsink	Various	Various	Aluminum. Approximate overall dimension 60mm by 15mm, min.1.5mm thick, secured to PWB by soldering (HS1)	NR
1	5	Heatsink	Various	Various	Aluminum. Approximate overall dimension 50mm by 6mm by 18mm, min.1.4mm thick, secured to PWB by soldering (HS2) (for 9.1-48V)	NR
			Various	Various	SPCC. Approximate overall dimension 50mm by 14mm by 38mm, min.1.2mm thick, secured to PWB by soldering (HS2) (for 9.1-48V)	
1	6	Insulation tape[4] (Not shown)	CHANG SHU LIANG YI TAPE INDUSTRY CO LTD	LY-XX	130°C (provided on heatsink)	cURus
			3M COMPANY	1350F-1		
				1350T-1		
			BONDTEC PACIFIC CO.,LTD	370S		
			JINGJIANG YAHUA	PZ series		
				CT series		
				WF series		
			JINGJIANG JINGYI	JY25-A		
1	7	Insulation tubing[4] (Not shown)	SHENZHEN WOER HEAT-SHRINKABLE MATERIAL CO LTD	RSFR	600V, 125°C (provided on heatsink or fuse or class I earth wire)	cURus
				RSFR-H		
				RSFR-HPF		
			QIFURUI ELECTRONICS CO	QFR-h	600V, 125°C (provided on heatsink or fuse or class I earth wire)	
			DONGGUAN SALIPT CO LTD	SALIPT S-901-300	Min. 300V, 125°C (provided on heatsink or fuse or class I earth wire)	
				SALIPT S-901-600		
			SHENZHEN WOLIDA TRADING CO LTD	RSFR-H	600V, 125°C (provided on heatsink or fuse or class I earth wire)	

4.0 Critical Components						
Photo #	Item no.[1]	Name	Manufacturer/ trademark[2]	SALIPT S-901-600	Technical data and securement means	Mark(s) of conformity [3]
			GUANGZHOU KAIHENG ENTERPRISE GROUP	K-2 (+)	Min. 300V, 125°C (provided on heatsink or fuse or class I earth wire)	
				K-2 (CB)		
			CHANGYUAN ELECTRONICS (SHENZHEN) CO LTD	CB-HFT	Min. 300V, 125°C (provided on heatsink or fuse or class I earth wire)	
1	8	X capacitor (Optional)	Cheng Tung Industrial Co., Ltd.	CTX	Max. 0.33uF, 310Vac, 110°C, type X1 or X2 (CX1)	cURus
			Ultra Tech Xiphi Enterprise Co. Ltd.	HQX	Max. 0.33uF, 275Vac, 110°C, type X2 (CX1)	
			Dain Electronics Co., Ltd.	MPX	Max. 0.33uF, 275Vac, 100°C, type X2 (CX1)	
				MEX		
				NPX		
			Sinhua Electronics	MPX	Max. 0.33uF, 300Vac, 110°C, type X2 (CX1)	
			Jiangsu Xinghua Huayu Co., Ltd.	MPX	Max. 0.33uF, 275Vac, 100°C, type X2 (CX1)	
			Hongzhi Enterprises Ltd.	MPX	Max. 0.33uF, 275Vac, 100°C, type X2 (CX1)	
			Tenta Electric Industrial Co. Ltd.	MEX	Max. 0.33uF, 275Vac, 100°C, type X2 (CX1)	
			Joey Electronics (Dong Guan) Co., Ltd.	MPX	Max. 0.33uF, 275Vac, 100°C, type X2 (CX1)	
			Yuon Yu Electronics Co. Ltd.	MPX	Max. 0.33uF, 275Vac, 100°C, type X2 (CX1)	
			Shenzhen Jinghao Capacitor Co.,	CBB62B	Max. 0.33uF, 275Vac, 100°C, type X2 (CX1)	
			Foshan Shunde Chuang Ge Electronic Industrial Co., Ltd.	MKP-X2	Max. 0.33uF, 275Vac, 100°C, type X2 (CX1)	
			Okaya Electric Industries Co. LTD	RE-Series	Max. 0.33uF, 275Vac, 100°C, type X2 (CX1)	
			Foshan Shunde Beijiao Hua Da Electric Industrial Co., Ltd.	HD-MKP	Max. 0.33uF, 275Vac, 100°C, type X2 (CX1)	
			VISHAY Capacitors Belgium NV	F 1772	Max. 0.33uF, 275Vac, 100°C, type X2 (CX1)	
			Winday Electronic Industrial Co., Ltd.	MPX series	Max. 0.33uF, 275Vac, 100°C, type X2 (CX1)	
1	9	Line filter (optional)	GlobTek/HAOPU WEI/HEJIA/BOA M	LF019	130°C (LF1)	NR

4.0 Critical Components						
Photo #	Item no.[1]	Name	Manufacturer/ trademark[2]	SALIPT S-901-600	Technical data and securement means	Mark(s) of conformity [3]
1	10	Line filter (optional)	GlobTek/HAOPUWEI/HEJIA/BOAM	LF018	130°C (LF2)	NR
1	11	Transformer	GlobTek	TF024	Input 100-240Vac, Output 5-6.5V, Class B, with insulation system listed below (T1)	NR
				TF025	Input 100-240Vac, Output 6.6-8.9V, Class B, with insulation system listed below (T1)	
				TF026	Input 100-240Vac, Output 9-13V, Class B, with insulation system listed below (T1)	
				TF027	Input 100-240Vac, Output 13.1-17V, Class B, with insulation system listed below (T1)	
				TF028	Input 100-240Vac, Output 17.1-24.9V, Class B, with insulation system listed below (T1)	
				TF029	Input 100-240Vac, Output 25-34.9V, Class B, with insulation system listed below (T1)	
				TF032	Input 100-240Vac, Output 35-48V,Class B, with insulation system listed below (T1)	
			BOAM	TF024	Input 100-240Vac, Output 5-6.5V, Class B, with insulation system listed below (T1)	NR
				TF025	Input 100-240Vac, Output 6.6-8.9V, Class B, with insulation system listed below (T1)	
				TF026	Input 100-240Vac, Output 9-13V, Class B, with insulation system listed below (T1)	
				TF027	Input 100-240Vac, Output 13.1-17V, Class B, with insulation system listed below (T1)	
				TF028	Input 100-240Vac, Output 17.1-24.9V, Class B, with insulation system listed below (T1)	
				TF029	Input 100-240Vac, Output 25-34.9V, Class B, with insulation system listed below (T1)	
				TF032	Input 100-240Vac, Output 35-48V,Class B, with insulation system listed below (T1)	
				TF024	Input 100-240Vac, Output 5-6.5V, Class B, with insulation system listed below (T1)	
				TF025	Input 100-240Vac, Output 6.6-8.9V, Class B, with insulation system listed below (T1)	
				TF026	Input 100-240Vac, Output 9-13V, Class B, with insulation system listed below (T1)	

4.0 Critical Components						
Photo #	Item no.[1]	Name	Manufacturer/ trademark[2]	SALIPT S-901-600	Technical data and securement means	Mark(s) of conformity [3]
			HAOPUWEI	TF027	Input 100-240Vac, Output 13.1-17V, Class B, with insulation system listed below (T1)	NR
				TF028	Input 100-240Vac, Output 17.1-24.9V, Class B, with insulation system listed below (T1)	
				TF029	Input 100-240Vac, Output 25-34.9V, Class B, with insulation system listed below (T1)	
				TF032	Input 100-240Vac, Output 35-48V,Class B, with insulation system listed below (T1)	
1	11a	-Insulation system	GLOBTEK INC	GTX-130-TM	Class B	cURus
			SHAN DONG BOAM ELECTRIC CO LTD	BOAM-01		
			WUXI HAOPUWEI ELECTRONICS CO LTD	ZT-130		
1	12	Y-Capacitor (Optional)	TDK-EPC CORPORATION	CD	Type Y1, max. 2200pF, min. 250V, min. 125°C (CY1, CY2)	cURus
			SUCCESS ELECTRONICS CO LTD	SE		
				SB		
			MURATA MFG CO LTD	KX		
			WALSIN TECHNOLOGY CORP	AH		
			JYA-NAY CO LTD	JN		
			HAOHUA ELECTRONIC CO	CT7		
			JERRO ELECTRONICS CORP	JX-series		
			WELSON INDUSTRIAL CO LTD	WD		
2	13	Heatsink	Various	Various	Aluminum. Approximate overall dimension 50mm by 22mm by 38mm, min.1.0mm thick, secured to PWB by soldering (HS2) (for 5-9V)	NR
			Various	Various	Aluminum. Approximate overall dimension 50mm by 22mm by 38mm, min.1.2mm thick, secured to PWB by soldering (HS2) (for 5-9V)	

4.0 Critical Components						
Photo #	Item no.[1]	Name	Manufacturer/ trademark[2]	SALIPT S-901-600	Technical data and securement means	Mark(s) of conformity [3]
			Various	Various	SPCC. Approximate overall dimension 50mm by 14mm by 38mm, min.1.2mm thick, secured to PWB by soldering (HS2) (for 5-9V)	
3	14	Optocoupler	LITE-ON Technology Corporation	LTV-817C	2MOPP at working voltage 250Vrms, 100°C (U2)	cURus
			Everlight Electronics Co., Ltd.	EL817		
			COSMO	K1010	Dti=0.6mm Int，dcr=4.0mm，EXT.dcr=5.0mm，thermal cycling test, 115℃ (U2)	
				KP1010		
			Fairchild Semiconductor Pte Ltd	H11A817B	Isulation voltage:850V; Transient overvoltage:6000V; CTI175; Int.Cr/Ext.Cr: ≥7.0/7.0mm; 30/110/21; (U2)	
				FOD817B		
			Toshiba Electronic Devices& Storage Corporation	TLP817FK	ti > 0.4mm Int, EXT.ci > r8.0mm, Isolation 3000Vac min., 110℃; thermal cycling test (U2)	
				TLP817KF		

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.

4) 2 layers of insulating tape or 1 layer of min. 0.4 mm thickness insulating tube can be used alternatively for wrapping around heatsink.

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 & 6-7 for details.
2. Mechanical Assembly - Components such as switches, fuseholders, connectors, wiring terminals and display lamps are mounted and prevented from shifting or rotating by the use of lockwashers, starwashers, or other mounting format that prevents turning of the component.
3. Corrosion Protection - All ferrous metal parts are protected against corrosion by painting, plating or the equivalent.
4. Accessibility of Live Parts - For adapter models, all uninsulated live parts in primary circuitry are housed within a non-metallic enclosure constructed with no openings and metal enclosure earthed with ventilation holes other than those specifically described in Sections 4 and 5.
5. Grounding - All exposed dead-metal parts and all dead-metal parts within the enclosure that are exposed are connected to the grounding lead of the power supply cord and the equipment grounding terminal.
6. Polarized Connection - This product is provided with a polarized power supply connection.
7. Internal Wiring - Internal wiring is routed away from sharp or moving parts. Internal wiring leads terminating in soldered connections are made mechanically secure prior to soldering. Recognized Component separable(quick disconnect) connectors of the positive detent type, closed loop connectors, or other types specifically described in the text of this report are also acceptable as internal wiring terminals. At points where internal wiring passes through metal walls or partitions, the wiring insulation is protected against abrasion or damage by plastic bushings or grommets. All internal wiring is contained in the recognized subassembly.
9. Markings - The product is marked as follows:
   1. Brand name: refer to sec. 2.0
   2. Model number: refer to sec. 2.0
   3. Ratings: refer to sec. 2.0
   4. Manufacturer: refer to sec. 1.0

7.0 Illustrations

Illustration 1 - Model list

Model	Output Voltage	Max. output current	Max. output power	Transformer
GT*43007-**05*	5 V	6A	30W	TF024 for 5-6.5Vdc TF025 for 6.6-8.9Vdc TF026 for 9-13Vdc TF027 for 13.1-17Vdc TF028 for 17.1-24.9Vdc TF029 for 25-34.9Vdc TF032 for 35-48Vdc
GT*43007-**07**	5.1-7V	6A	30W	
GT*43007-**09**	7.1-9V	5A	45W	
GT*43007-**12**	9.1-12V	5.0A	60W	
GT*43007-**15**	12.1-15V	5.0A	60W	
GT*43007-**18**	15.1-18V	4.0A	60W	
GT*43007-**24**	18.1-24V	3.31A	60W	
GT*43007-**36**	24.1-36V	2.50A	60W	
GT*43007-**48**	36.1-48V	1.66A	60W	

7.0 Illustrations

Illustration 2 - Spacings

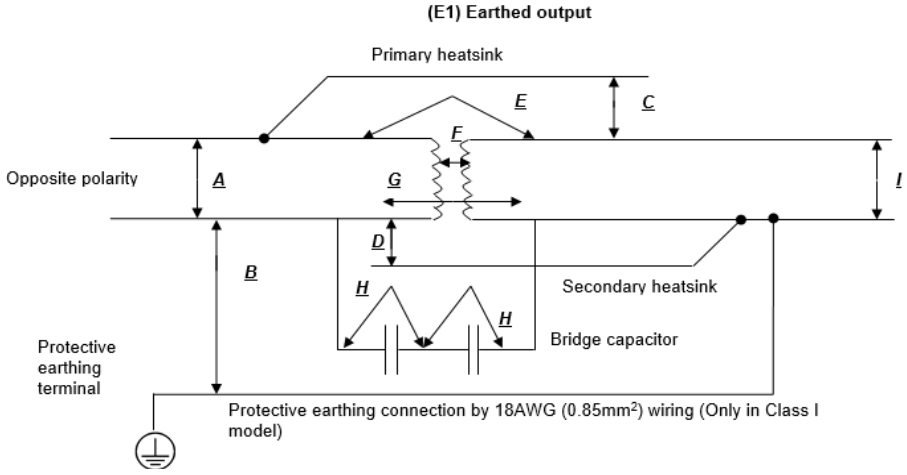


TABLE: INSULATION DIAGRAM		P
Pollution degree ..... :	2	—
Overvoltage category ..... :	II	—
Altitude ..... :	5000m	—
Additional details on parts considered as applied parts ..... :	☒ None ☐ Areas _____ (See Clause 4.6 for details)	—

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	MOOP	IIIb	240	340	3.0	3.0[2]	3.2	3.2	Opposite polarity of mains part
B	MOPP	IIIb	240	--	4.0	3.3[2]	4.0	3.8	Mains parts to PE terminal (Along PCB trace)
C	2MOPP	IIIb	240[1]	--	8.0	6.5[2]	10.0[4]	10.0[4]	Primary heatsink to secondary circuit
D	2MOPP	IIIb	240[1]	--	8.0	6.5[2]	10.0[4]	10.0[4]	Primary circuit to secondary heatsink
E	2MOPP	IIIb	240[1]	--	8.0	6.5[2]	10.0[3]	7.7	Primary side to secondary side (Optocoupler)
F	2MOPP	IIIb	324[1]	--	10.0	9.0[2]	11.0[5]	11.0	Primary side (including ferrite) to secondary pin-out (Transformer)
G	2MOPP	IIIb	240[1]	--	8.0	6.5[2]	10.0[3]	7.7	Mains parts to secondary parts (Nearest points along PCB trace)
H	MOPP (Each) x 2	IIIb	240[1]	--	8.0	6.6[2]	10.0[3]	9.0	Primary side to secondary side (Y capacitor x 2)
I	2MOOP	IIIb	Max. 48Vdc	--	--	--	--	--	Accessible parts per 8.4.2 c)

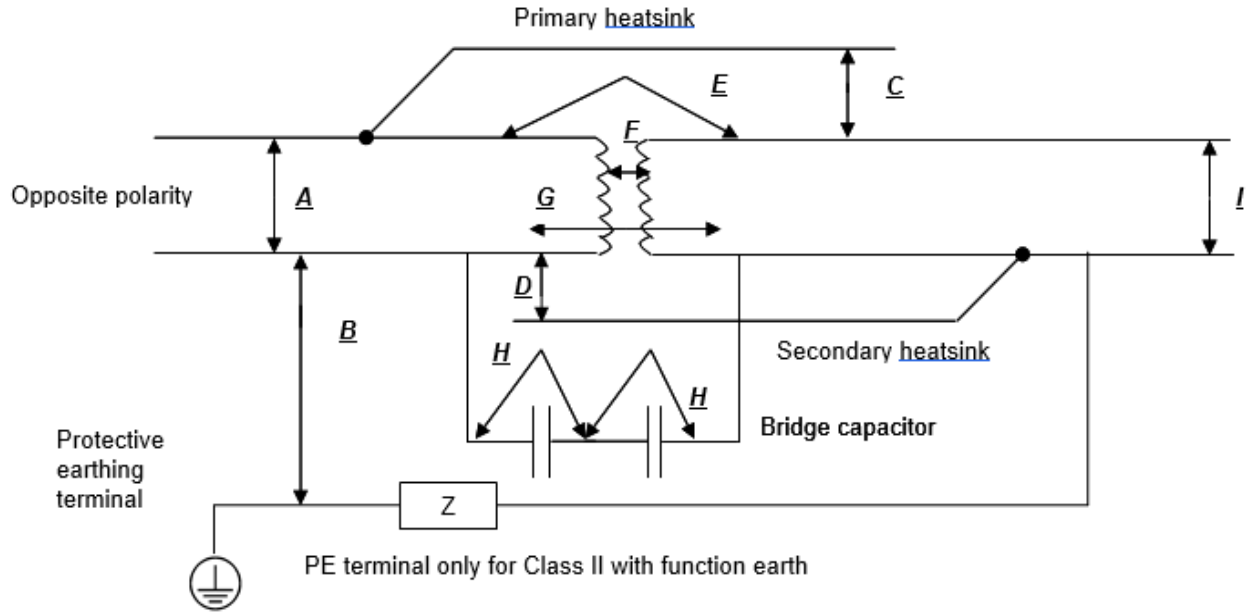
Supplementary Information:

1) The working voltage is highest measured value which acquired by testing all the models listed in the report at the rated input voltage, but not less than the rated input voltage.
2) Multiplication factor for MOOP: 1.48; Multiplication factor for MOPP: 1.29.
3) There is a slot wide > 1 mm between these two parts.
4) Two layers of insulating tape or 0.4mm thickness insulating tube wrap around the heatsink.
5) The whole ferrite core is wrapped around 2 layers of insulating tape.

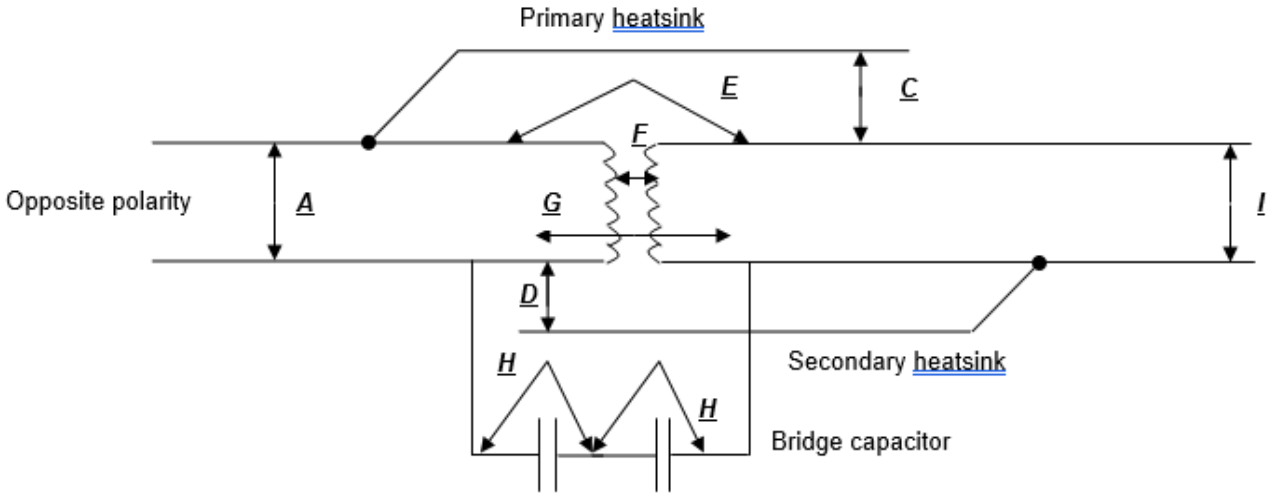
7.0 Illustrations

Illustration 6 - Spacings (Cont.)

(E2) Class II, FE, Earthed output



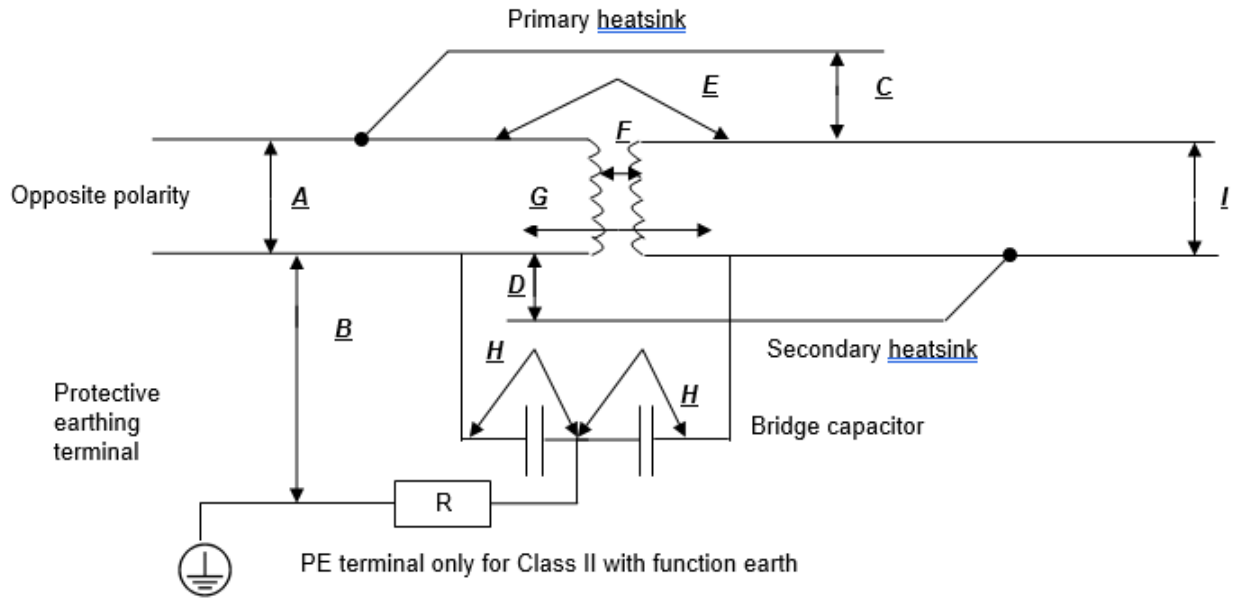
(F1) Class II / Double insulated



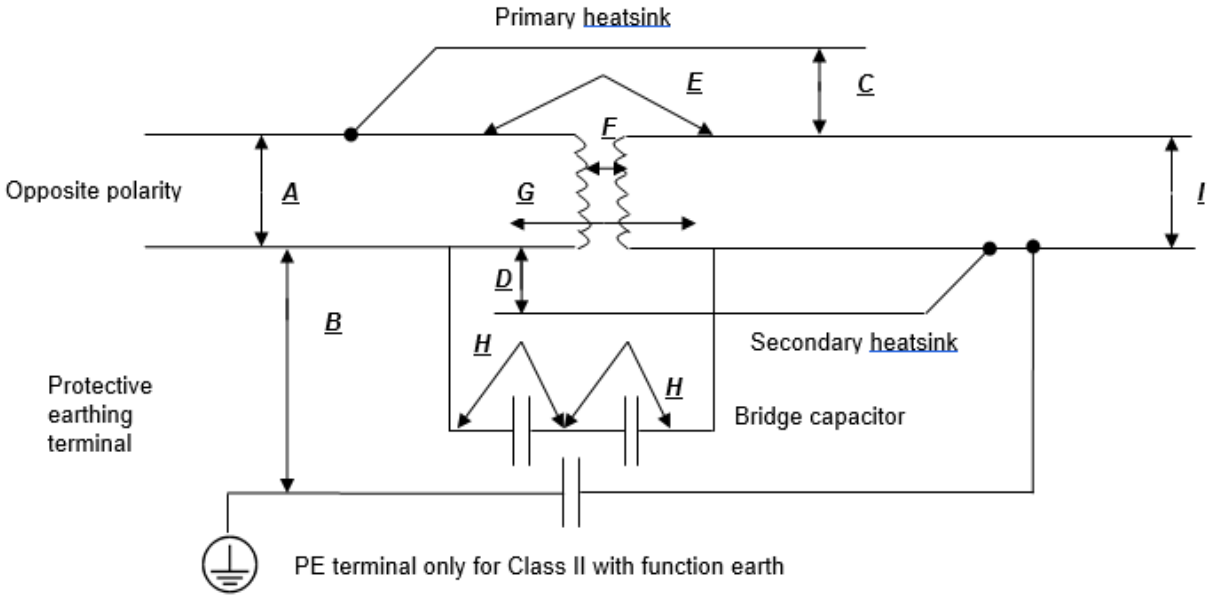
7.0 Illustrations

Illustration 7 - Spacings (Cont.)

(F2) Isolated functional earth



(F3) Floating output/ Isolated common by capacitor



8.0 Test Summary						
Evaluation Period	2014-10-21 ~ 2014-11-10				Project No.	140900435SHA
Sample Rec. Date	21-Oct-2014	Condition	Prototype		Sample ID.	0141021-12-001
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	ANSI/AAMI ES60601-1:2005/A1:2012 Issued: 2012/08/20 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance, Amendment 1; CAN/CSA-C22.2 No. 60601-1:14, Third Edition Issued: 2014/03/01 - Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance. 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
Excessive Temperature	11.1
Single Fault Conditions	13.2
Transformer Short-Circuit	15.5.1.2
Transformer Overload	15.5.1.3
Transformer Dielectric Strength	15.5.2

Evaluation Period	3-Jul-2017 to 31-Dce-2020				Project No.	201201441SHA
Sample Rec. Date	3-Jul-2017	Condition	Prototype		Sample ID.	0170628-76
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	AAMI ES60601-1:2005 +A1 CSA C22.2#60601-1:2014 Ed.3 Clause
Power Input	4.11
Creepage & Clearance Measurements	8.9.4
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:	Yann Yan	Reviewed by:	Jack Cheng
Title:	Project engineer	Title:	Project 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.

The Applicant will be notified, in writing, via the applicable contact methods, as defined in Section 1.0, when these components must be selected and sent to Component Evaluation Center (CEC) for re-evaluation.

Due to particular testing requirements, some components may be requested to be shipped to specific labs. Thus, specific shipment destination(s) for each sample will be provided in the written notification.

Managing CEC Location:
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

Grounding Continuity Test

11.1 Dielectric Voltage Withstand Test

Method

One hundred percent of production of the products covered by this Report shall be subjected to a routine production line dielectric withstand test.

The test shall be conducted on products, which are fully assembled. Prior to applying the test potential, all switches, contactors, relays, etc., should be closed so that all primary circuits are energized by the test potential. If all primary circuits cannot be tested at one time, then separate applications of the test potential shall be made.

The test voltage specified below shall be applied between primary circuits and accessible dead-metal parts. The test voltage may be gradually increased to the specified value but must be maintained at the specified value for one second or one minute as required.

Test Equipment

The test equipment shall incorporate a transformer with an essentially sinusoidal output, a means to indicate the applied test potential, and an audible and/or visual indicator of dielectric breakdown.

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 less than 500VA.

If the rated output of the test equipment is 500VA or more, the applied test potential may be indicated by either:

1 - a voltmeter in the primary circuit;

2 - a selector switch marked to indicate the test potential; or

3 - a marking in a readily visible location to indicate the test potential for test equipment having a single test potential output.

In cases 2 and 3, the test equipment shall include a lamp or other visual means to indicate that the test potential is present at the test equipment output. All test equipment shall be maintained in current calibration.

Products Requiring Dielectric Voltage Withstand Test:

Product	Test Voltage	Test Time
Between L/N and PE terminal for Class I models only	1500Vac	1 s
Between L/N and secondary output for Class II models only	4000Vac	1 s
Product- One sample from each shipment of Section 4.0 item 11:	**Test Voltage**	**Test Time**
Between primary circuit and secondary output	4000Vac	1 min
Between secondary circuit and core	4000Vac	1 min

11.2 Grounding Continuity Test

Method

Each product listed below shall be subjected to a test to determine that there is continuity between accessible dead-metal parts of the product and the grounding pin or blade of the attachment plug.

If all accessible dead metal is connected, only a single test need be performed. A visual or audible device (ohmmeter, buzzer, etc.) may be used to indicate grounding continuity.

Products Requiring Grounding Continuity Test:

Class I models covered by this Report.

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
19-Feb-2021		1.0	-	Updated the standard information from "ANSI/AAMI ES60601-1:2005/A1:2012 Issued: 2012/08/20 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance, Amendment 1; CAN/CSAC22.2 No. 60601-1:14, Third Edition Issued: 2014/03/01 - Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance." to "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 (R2018) [CSA C22.2#60601-1:2014 Ed.3]"according to EDGE.
201201441SHA		1.0	-	Updated the contact of applicant from "Hans Moritz" to "Michael Krakovyak".
		2.0	-	Updated the brand name from "GlobTek“ to GlobTek, Inc.
		2.0	-	Updated the description of models from "GT*43007-***** (The 1st "*" can be 'M' or '-' or 'H'; the 2nd "*" can 'A', 'B' or 'C'; the 3rd "*" can be "01" to "60" with interval of 1. The 4th "*" can be "05", "07", "09", "12", "15", "18", "24", "36" or "48"; The 5th "*" can be "-0.1" to "-11.9" with interval of 0.1 or blank; The 6th "*" can be "-F" or "-FW".)" to "GT followed by M, - or H; followed by 43007-; followed by A, B or C; followed by 01 to 60; followed by 05, 07, 09, 12, 15, 18, 24, 36 or 48; may be followed by -0.1 to -11.9; followed by -F or -FW."
		2.0	-	Updated the rated frequency of the product from “50-60Hz” to “50-60Hz or 50/60Hz”.
		3.0	4-21	Added new photos.
	Yann Yan/ Jack Cheng	4.0	1	Added alternative PCB manufactured by WALEX ELECTRONIC (WUXI) CO LTD, DONGGUAN HE TONG ELECTRONICS CO LTD, CHEERFUL ELECTRONIC (HK) LTD, DONGGUAN DAYSUN ELECTRONIC CO LTD, KUOTIANG ENT LTD, YUANMAN PRINTED CIRCUIT CO LTD, SUZHOU XINKE ELECTRONICS CO LTD, KUNSHAN CITY HUA SHENG CIRCUIT BOARD CO LTD, JIANGSU DIFEIDA ELECTRONICS CO LTD,HUIZHOU SHUNJIA ELECTRONICS CO LTD, SHANGHAI H-FAST ELECTRONIC CO LTD in critical components list, no test required.
		4.0	2	Added alternative fuse manufactured by Bel Fuse Ltd., Zhongshan Lanbao Electrical Appliances Co., Ltd., Dongguan Better Electronics Technology Co., Ltd., Hollyland Compoany Limited, Sunny East Enterprise Co. Ltd., Conquer Electronics Co., Ltd. in critical components list, no test required.

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
		4.0	8	Added alternative X capacitor manufactured by Tenta Electric Industrial Co. Ltd., Joey Electronics (Dong Guan) Co., Ltd., Yuon Yu Electronics Co. Ltd., Shenzhen JinghaoCapacitor Co.,, Foshan Shunde Chuang GeElectronic Industrial Co., Ltd., Okaya Electric IndustriesCo. LTD, Foshan Shunde Beijiao Hua DaElectric Industrial Co., Ltd., VISHAY Capacitors Belgium NV, Winday ElectronicIndustrial Co., Ltd. in critical components list, no test required.
		4.0	14	Added alternative optocoupler manufactured by COSMO, Fairchild Semiconductor Pte Ltd, Toshiba Electronic Devices& Storage Corporation in critical components list, no test required.
		6.0	1	Updated the illustration number from "2a-2b" to "2, 6-7"
		6.0	8	Deleted Schematics description.
		6.0	9	Updated Marking description from "9. Markings - The product is marked as follows: brand name, model number, electrical ratings, manufacturer. Refer to Illustration No. 5 for details." to "9. Markings - The product is marked as follows: 1. Brand name: refer to sec. 2.0 2. Model number: refer to sec. 2.0 3. Ratings: refer to sec. 2.0 4. Manufacturer: refer to sec. 1.0".
		6.0	10	Deleted Cautionary Markings description.
		6.0	11	Deleted Safety Instructions description.
		7.0	1	Increase the max. output power for model GT*43007-**12** from 45W to 60W.
		7.0	2	Combined illustration 2a and illustration 2b to illustration 2- Spacings; Updated the insulation diagram and table.
		7.0	3	Deleted illustration 3 for Schematics.
		7.0	4a-4c	Deleted all illustrations for PCB layout.
		7.0	5	Deleted illustration 5 for Marking.
		7.0	6-7	Added new grounding methods in insulation diagrams.
		8.0	-	Added a new test block.
		8.1	-	Revised with new signature.
		11.0	-	Added dielectric voltage withstand test for unlisted transformer.