1.0 Reference and Address					
Report Number	180401376SHA-001	Original Issued:	30-Jul-2018	Revised:	None
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 [CSA C22.2#60601-1:2014 Ed.3] 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]				

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.106	Phone	86 512 6279 0301 Ext.189
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Email	krakovyakm@globtek.us	Email	demon.zhou@globtek.cn

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. 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. 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. The products are not intended to be used in maximum ambient temperature exceed of 40 °C . The products are not intended to use in environment which altitude exceed 5000m.The insulation construction of EUT is evaluated as 2MOPP in this report as customer's request. This product should be purchased together with the end equipment, it can not be sold separately.
Models	GT followed by M, - or H; followed by 961600P or 961800P; followed by 01 to 180; followed by 12 to 54; followed by -T2, -T2A, -T3, -T3A, -TW, -TP; may be followed by six characters. GT followed by M, - or H; followed by 961600P or 961800P; followed by 01 to 180; followed by 12.0 to 54.0; followed by -T2, -T2A, -T3, -T3A, -TW, -TP; may be followed by six characters.
Model Similarity	Model Similarity: GT*961600P**** , GT*961800P**** series 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 "180", with interval of 1 The 3rd "*" denote the standard rated output voltage designation, which can be "12" to "54" or "12.0" to "54.0" in 0.1V increments The 4th"*" =-T2 means desktop class II with C8 AC inlet =-T2A means desktop class II with C18 AC inlet =-T3 means desktop class I with C14 AC inlet =-T3A means desktop class I with C6 AC inlet =-TW means desktop with input wires without plug =-TP means desktop with power cord and plug The last * denote any six character = 0-9 or A-Z or ()[] or – or blank for marketing purposes.
Ratings	Input: 100-240V~, 50-60Hz, 2.2A; Output: 12-54VDC, Max.13.33A, Max. 180W
Other Ratings	NA

2.0 Product 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. 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. 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.
Conditions of Acceptability	Scope of Power Supply evaluation defers the following clauses to be determined as part of the end product investigation: Clause 7.5 (Safety Signs), 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.), Clause 8.11.5 (Mains Fuse with High Breaking Capacity), Clause 9 (ME Hazard), except 9.1 and 9.3 are evaluated, Clause 10 (Radiation), Clause 11.7 (Biocompatibility), Clause 14 (PEMS), Clause 16 (ME Systems) , Clause 17 (EMC) The high breaking capacity of mains fuse is tested with mains supply of which capability is 150KVA

3.0 Product Photographs

Photo 1 - External view of EUT

Photo 2 - External view of EUT

3.0 Product Photographs

Photo 3 - Internal view with Top Enclosure Removed

Photo 4 - Internal view with Lower Enclosure Removed

3.0 Product Photographs

Photo 5 - Internal view with Top Metal Cover Removed

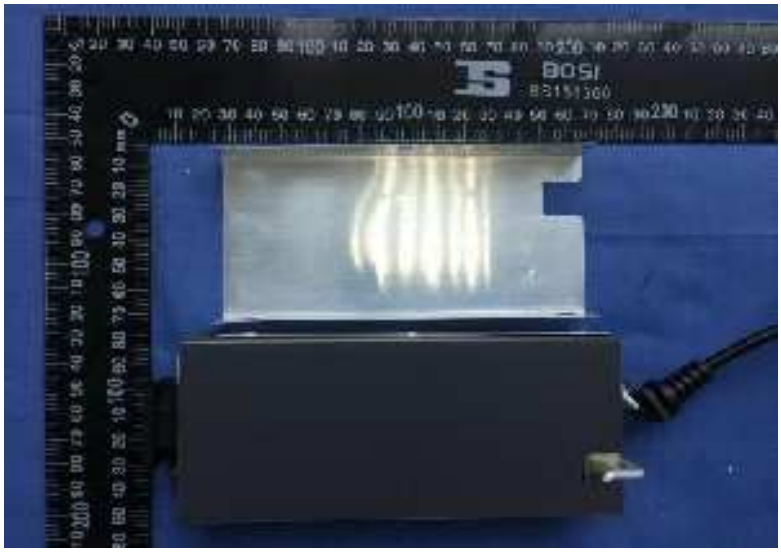


Photo 6 - Internal view with Lower Metal Cover Removed

3.0 Product Photographs

Photo 7 - Internal view with Insulation Sheet Removed

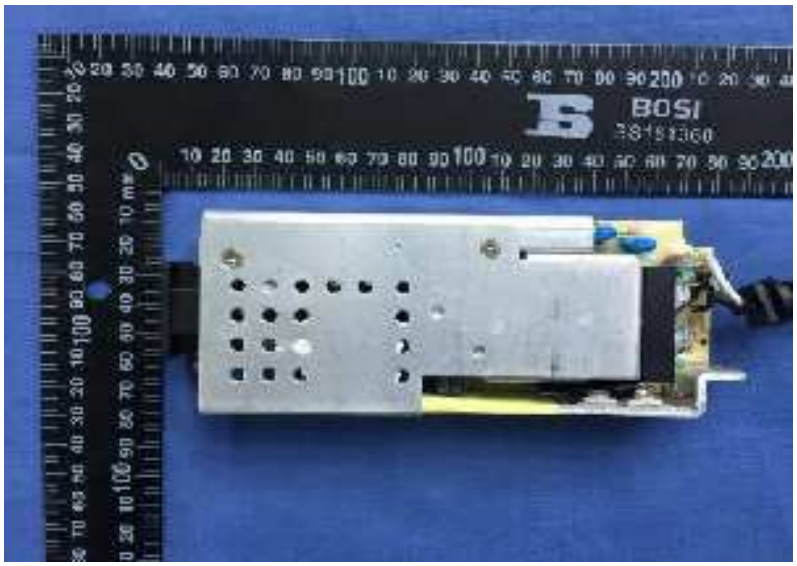
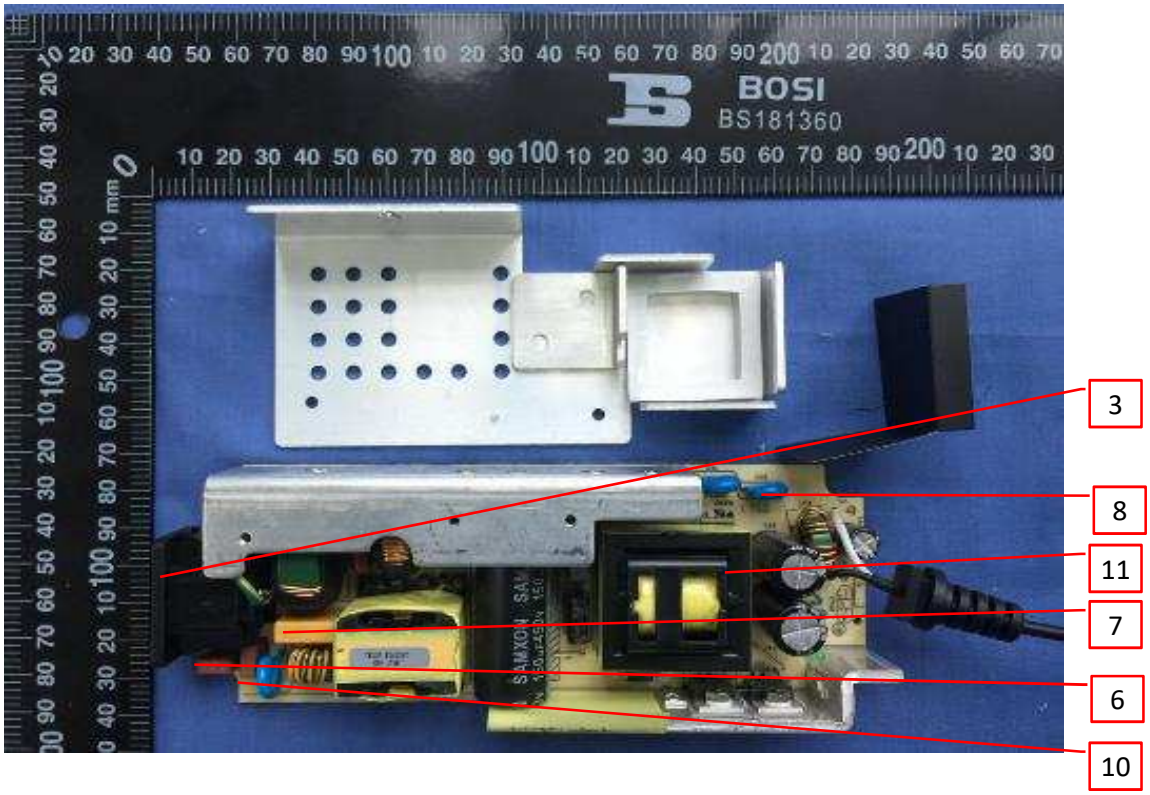


Photo 8 - PCB Top Side (Class I)



3.0 Product Photographs

Photo 9 - PCB Top Side (Class II)

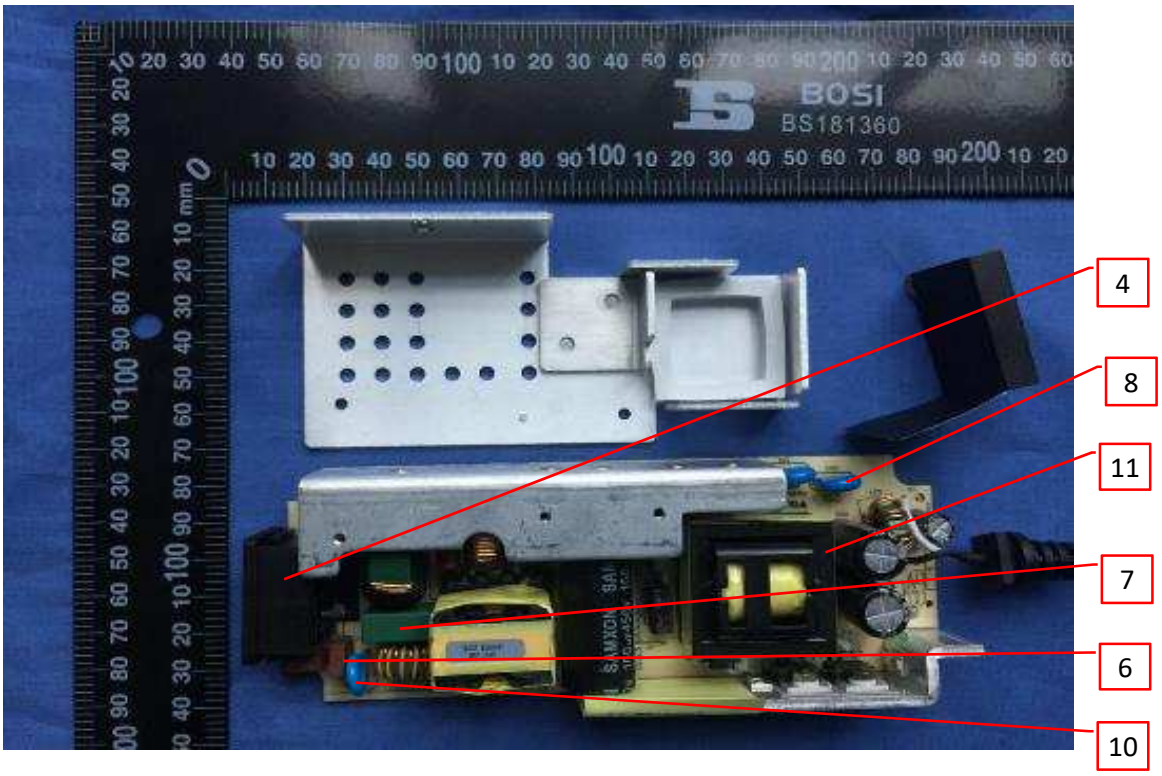
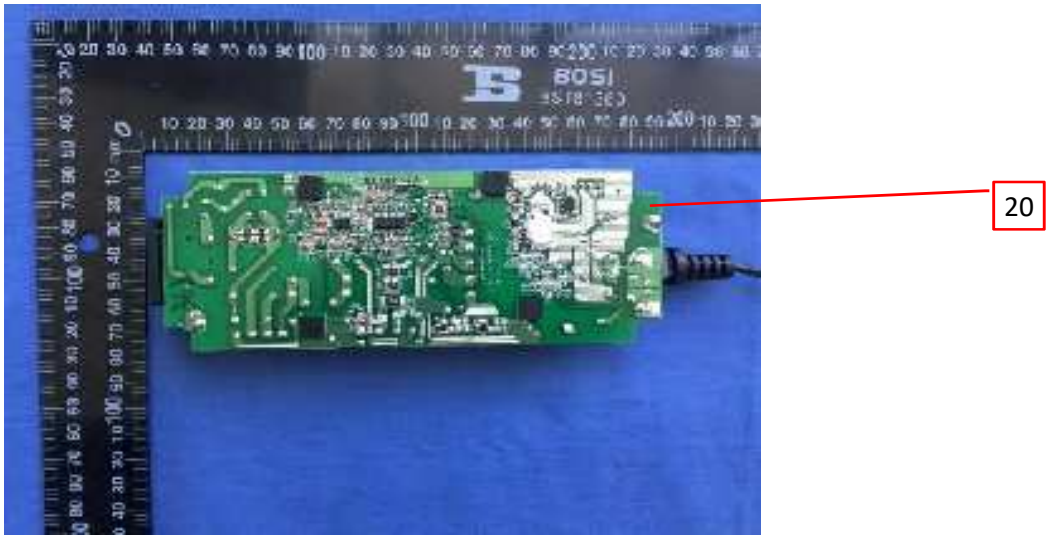


Photo 10 - PCB Bottom Side(12.0-36.0V model, Class I)



3.0 Product Photographs

Photo 11 - Bottom Side(36.1-54V model, Class I)

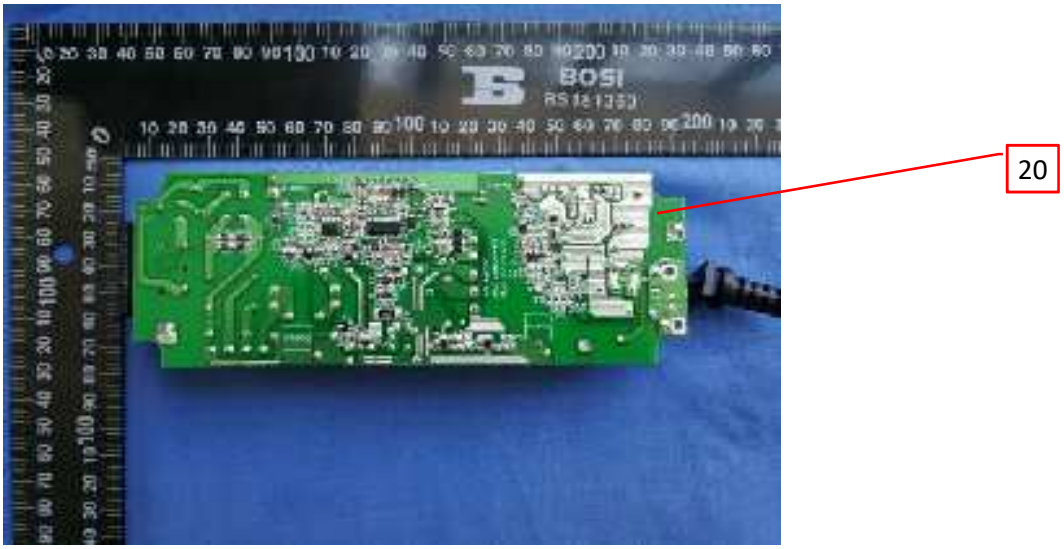
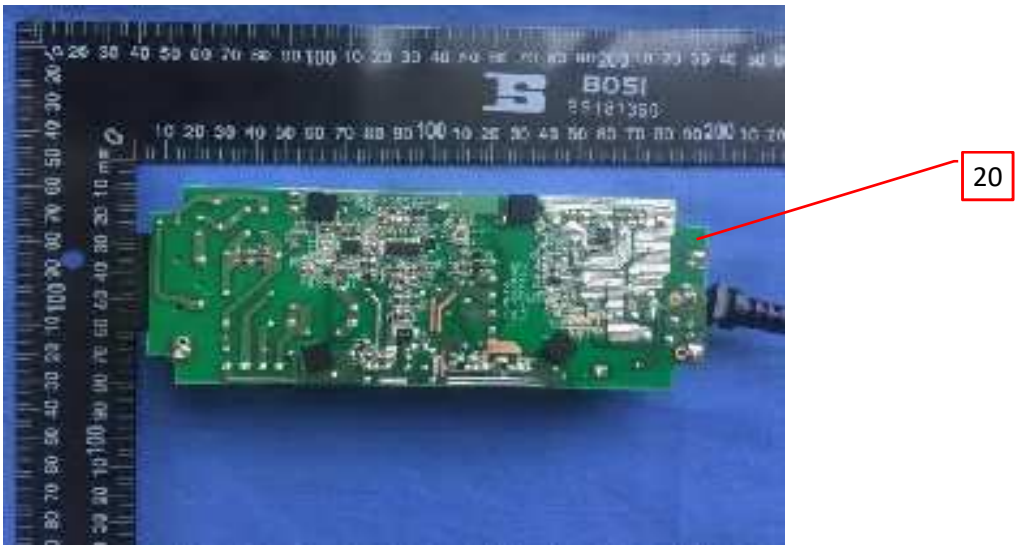
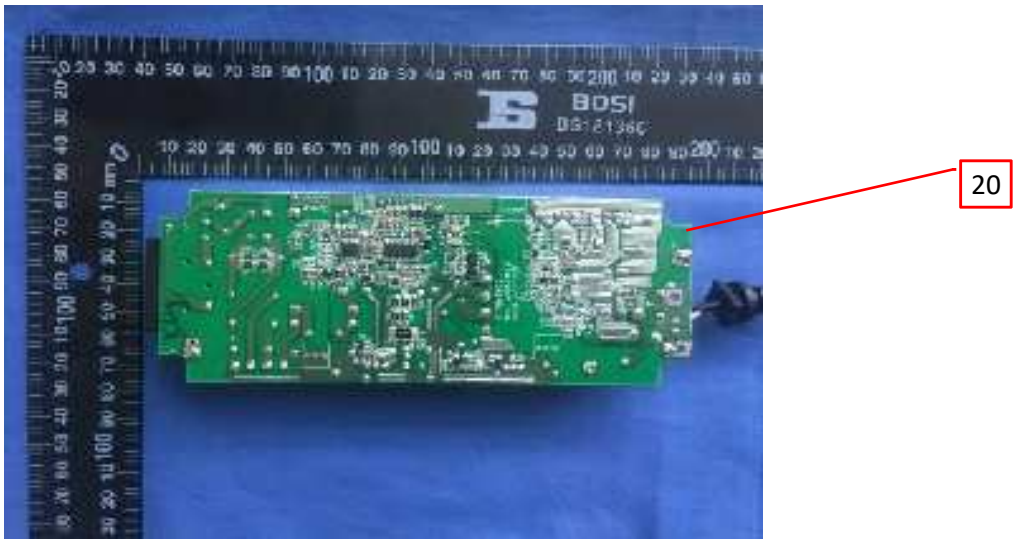


Photo 12 - PCB Bottom Side(12.0-36.0V model, Class II)



3.0 Product Photographs

Photo 13 - PCB Bottom Side(54V model, Class II)



3.0 Product Photographs

Photo 14 - External view of transformer

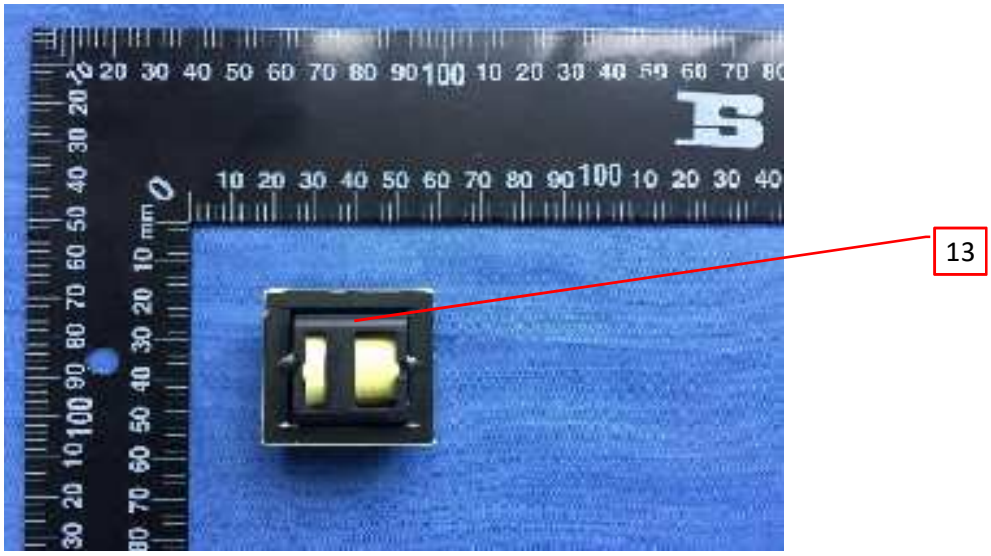
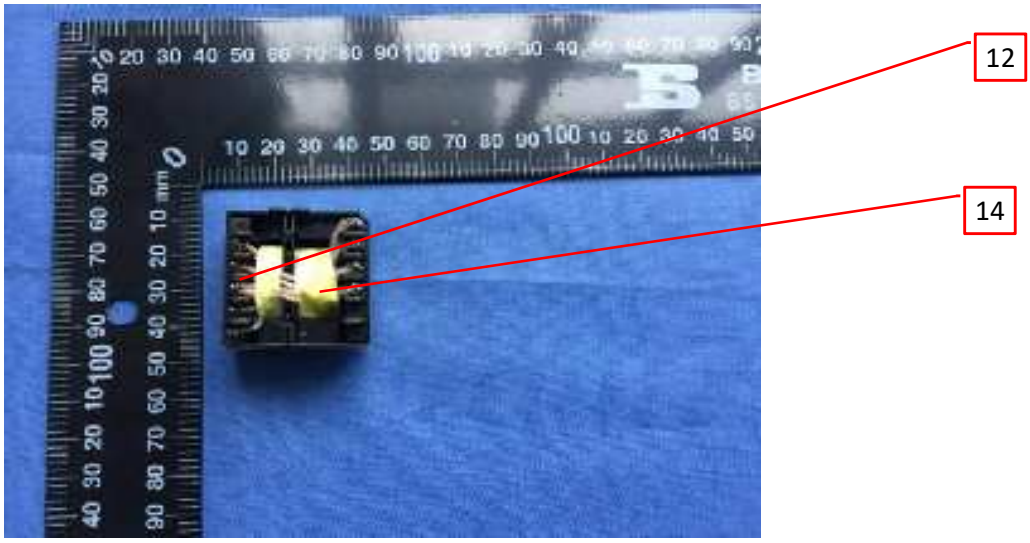


Photo 15: Internal view of transformer



3.0 Product Photographs

Photo 16 - Cord Connected Model Without Plug

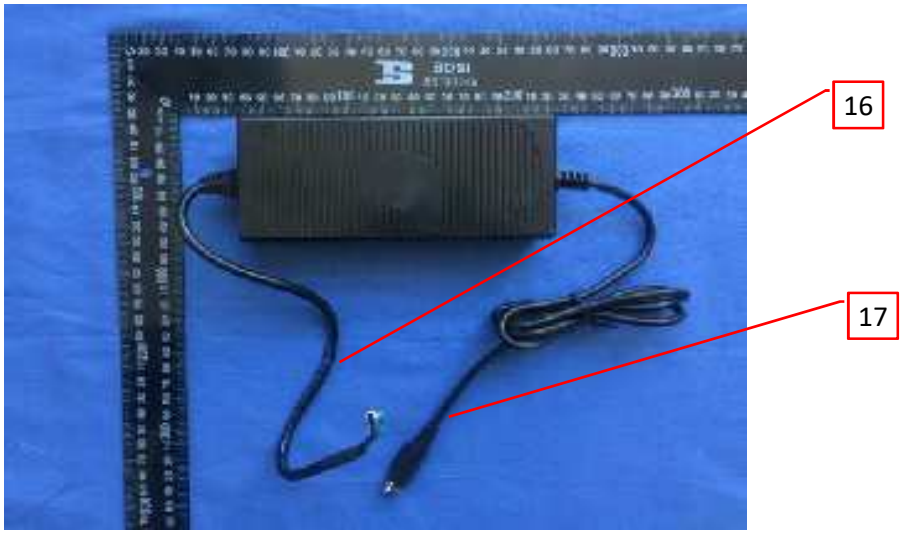


Photo 17 - Cord Connected Model With Plug

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, 3,4	1	Enclosure	SABIC INNOVATIVE PLASTICS	SE1X	Min.V-1, min. 2.0mm thickness, 105°C	cURus
				SE1		
				SE100		
				HF500R		
				CX7211		
				EXCY0098		
				C2950		
				945		
			SABIC JAPAN L L C	SE1X	Min.V-1, min. 2.0mm thickness, 105°C	
				SE1		
				HF500R		
				CX7211		
				C2950		
				945		
			TEIJIN CHEMICALS LTD	LN-1250P	Min. V-0 at 1,5 mm thickness, 115°C	
				LN-1250G		
			COVESTRO DEUTSCHLAND AG [PC RESINS]	6485	Min. V-0 at 1,5 mm thickness, 115°C	
			Various	Various	Min. V-1, min.1.5 mm thickness, 105°C	
8	2 (not shown)	CN1 Class I units C6 type Appliance inlet	+ Zhejiang LECI Electronics	DB--6	250 Vac; 2,5A; 3 pins, 75°C	cURus
			+ Tecx-Unions Technology Corp	TU--333	250 Vac; 2,5A; 3 pins	
			+ Rich Bay Co Ltd	R--30790	250 Vac; 2,5A; 3 pins	
			+ Sun Fair Electric Wire & Cable (HK) Co Ltd	S--02	250 Vac; 2,5A; 3 pins	
			+ DLK Electronics Technology Co Ltd	CDJ--2	250 Vac; 2,5A; 3 pins	
			Inalways Corp.	724	250 Vac; 2,5A; 3 pins	
			Zhe Jiang Bei Er jia	ST-A04-002	250 Vac; 2,5A; 3 pins	
			Rong Feng Industrial Co., Ltd.	RF-190	2,5A, 250Vac	

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]
8	3	CN1 Class I units C14 type Appliance inlet	+ Zhejiang LECI Electronics	DB--14	250 Vac; 10A; 3 pins	cURus
			+ TecxUnions Technology Corp	TU-301-S	250 Vac; 10A; 3 pins	
				TU-301-SP		
			+ Rich Bay Co Ltd	R-301SN	250 Vac; 10A; 3 pins	
			+ Sun Fair Electric Wire & Cable (HK) Co Ltd	SS-120	250 Vac; 10A; 3 pins	
			Inalways Corp.	711	250 Vac; 10A; 3 pins	
			Zhe Jiang Bei Er jia	ST-A01-003J	250 Vac; 10A; 3 pins	
			Rong Feng Industrial Co., Ltd.	SS-120	2,5A, 250Vac	
9	4	CN1 Class II units C8 type Appliance inlet	+ Zhejiang LECI Electronics	DB--8	250 Vac; 2,5A; 2 pins	cURus
			+ Delikang Electronics Technology Co Ltd	CDJ--8	250 Vac; 2,5A; 2 pins	
			+ Rich Bay Co Ltd	R-201SN90	250 Vac; 2,5A; 2 pins	
			+ Sun Fair Electric Wire & Cable (HK) Co Ltd	S--01	250 Vac; 2,5A; 2 pins	
			+ Tecx-unions Technology Corp	SO--222 series	250 Vac; 2,5A; 2 pins	
			Inalways Corp.	721	250 Vac; 2,5A; 2 pins	
			Zhe Jiang Bei Er jia	ST-A03-005	250 Vac; 2,5A; 2 pins	
			Rong Feng Industrial Co., Ltd.	RF-180	2,5A, 250Vac	

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	5 (not shown)	CN1 Class II units C18 type Appliance inlet	Rong Feng Industrial Co.,Ltd	SS-120A	10A,250V	cURus
			RICH BAY CO LTD	R-301SN	10A,250V	
8,9	6	Fuse	Conquer Electronics Co., Ltd.	MST series	T4A, 250V (F1,F2), F2 is optional	cURus
			Ever Island Electric Co., Ltd. And Walter Electric	2010		
			+ Zhongshan Lanbao Electrical Appliances	RTI--10		
			Bel Fuse Ltd.	RST Serie		
			Cooper Bussmann LLC	SS-5		
			Dongguan Better	932		
			Cooper Bussmann Inc.	SS-5		
			Shenzhen Lanson Electronics	SMT		
			Conquer Electronics Co., Ltd.	MET		

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]
8,9	7	X capacitor	Cheng Tung Industrial Co., Ltd.	CTX	Max 0.47µF, Min.300V,105°C X1 or X2 (CX1)	cURus
			Tenta Electric Industrial Co. Ltd.	MEX	Max 0.47µF, Min.250V,100°C X1 or X2 (CX1)	
			Joey	MPX	Max 0.47µF, Min.300V,110°C X1 or X2 (CX1)	
			Ultra Tech Xiphi Enterprise Co. Ltd.	HQX	Max 0.47µF, Min.250V,110°C X2 (CX1)	
			YUON YU ELECTRONICS CO	MPX	Max 0.47µF, Min.250V,100°C X2 (CX1)	
			SINHUA ELECTRONICS (HUZHOU) CO LTD	MPX	Max 0.47µF, Min.300V,110°C X1 or X2 (CX1)	
			Jiangsu Xinghua Huayu Electronics Co., Ltd.	MPX	Max 0.47µF, Min.250V,100°C X2 (CX1)	
			Dain Electronics Co., Ltd.	MEX MPX NPX	Max 0.47µF, Min.250V,110°C X1 or X2 (CX1)	
			Shenzhen Jinghao Capacitor Co., Ltd.	CBB62B	Max 0.47µF, Min.250V,110°C X2 (CX1)	
			Various	Various	Max 0.47µF, Min.250V,100°C X1 or X2 (CX1)	

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]
8,9	8	Y capacitor	TDK-EPC Corporation, Capacitors Group Circuit Devices Business Group	CD	Min. 250Vac; max. 2200pF; min. Y1 (CY1,CY2) (CY2, Optional)	cURus
			Success Electronics Co., Ltd.	SE	Min. 250Vac; max. 2200pF; min. Y1 (CY1,CY2) (CY2, Optional)	
				SB		
			Walsin Technology Corp.	AH	Min. 250Vac; max. 2200pF; min. Y1 (CY1,CY2) (CY2, Optional)	
			Haohua Electronic Co.	CT 7	Min. 250Vac; max. 2200pF; min. Y1 (CY1,CY2) (CY2, Optional)	
			JERRO ELECTRONICS CORP	JX	Min. 250Vac; max. 2200pF; min. Y1 (CY1,CY2) (CY2, Optional)	
			JYH CHUNG ELECTRONICS CO LTD	JD	Min.400Vac; max. 2200pF; min. Y1 (CY1,CY2) (CY2, Optional)	
			Murata Mfg Co Ltd	KX Series	Min. 250Vac; max. 2200pF; min. Y1 (CY1,CY2) (CY2, Optional)	
			JYA-NAY CO LTD	JN	Min. 250Vac; max. 2200pF; min. Y1 (CY1,CY2) (CY2, Optional)	
			Xiangtai Electronic (Shenzhen) Co., Ltd.	YO-series	Min. 250Vac; max. 2200pF; min. Y1 (CY1,CY2) (CY2, Optional)	
			JUHONG ELECTRONICS LTD	JB-series	Min. 250Vac; max. 2200pF; min. Y1 (CY1,CY2) (CY2, Optional)	
			WELSON INDUSTRIAL CO LT D	WD	Min. 250Vac; max. 2200pF; min. Y1 (CY1,CY2) (CY2, Optional)	
			Various	Various	Min. 250Vac; max. 2200pF; min. Y1 (CY1,CY2) (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]
8	9 (not shown)	Photo Coupler	Everlight Electronics Co., Ltd.	EL817	Dti=0.5mm Int. dcr=6.0mm EXT.dcr=7.7mm,thermal cycling test,110°C (U4)	cURus
			COSMO Electronics	K1010	Dti=0.6mm Int. (U4)	
				KP1010		
			Lite-On Technology Corporation	LTV-817	Dti=0.8mm EXT. dcr=7.8mm,thermal cycling test,110°C (U4)	
			Fairchild Semiconductor Ltd	H11A817B	Insulation voltage: 850V; Transient overvoltage: 6000V; CTI175; Int. Cr/ Ext. Cr: ≥7,0/ 7,0 mm; 30/110/21 (U4)	
				FOD817B		
			Sharp Corporation ElectronicComponents and Devices Group	PC817	Insulation voltage: 890V; Transient overvoltage: 9000V Int. Cr/ Ext. Cr: 7,62/ 7,62 mm; 30/110/21 (U4)	
			Bright Led Electronics Corp.	BPC-817 A	Dti=0.4mm EXT. dcr=7.0mm,thermal cycling test,110°C (U4)	
				BPC-817 B		
				BPC-817 C		
				BPC-817 D		
				BPC-817 L		
				BPC-817MBPC-817 S		
			+ TOSHIBA	TLP781F	Dti> 0,4mm, Ext cr> 8,0mm, Isolation 3000Vac min., 110°C min., Thermal cycling test (U4)	

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]
8,9	10	Varistor	TKS	TVR10471K TVR14471K	Max. Continuous voltage: min 300Vac(rms), 105°C	cURus
			Centra	CNR-10D471K CNR-14D471K	Max. Continuous voltage: min 300Vac(rms), 105C The coating is V-0 MOV1(optional)	
			Success Electronics Co Ltd	SVR10D471K SVR14D471K	Max. Continuous voltage: min 300Vac(rms), 105C The coating is V-0 MOV1(optional)	
			Walsin	VZ14D471K VZ10D471K	Max. Continuous voltage: min 300Vac(rms), 85°C The coating is V-0 MOV1(optional)	
			Lien Shun Electronics Co., Ltd.	14D471K 10D471K	Max. Continuous voltage: min 300Vac(rms), 105°C The coating is V-0 MOV1(optional)	
			CERAMATE	GNR10D471K GNR14D471K	Max. Continuous voltage: min 300Vac(rms), 105°C The coating is V-0 MOV1(optional)	
			Brightking	14D471K 10D471K	Max. Continuous voltage: min 300Vac(rms), 105°C The coating is V-0 MOV1(optional)	
			Joyin Co., Ltd.	10N471K 14N471K	300V rms; 385V d.c., 3kA, 8/20µs 85°C MOV1(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]
8,9	11	Transformer	GlobTek BOAM Haopuwei	TF081 TF082 TF083 TF084 TF085 TF086 TF087 TF088 TF089 TF090 TF091 TF092	Class B Ratings see illustration No(s). 6. Dimension see illustration No(s). 7. Winding specificaiton see illustration No(s).8 to 8c.	NR
15	12	Triple-insulated wire	Great Leoflon Industrial Co., Ltd.	TRW (B) Serie(s)	Class B, reinforced insulation Used for secondary wire (B) = Tinned copper	cURus
			COSMOLINK CO. Ltd.	TIW-M Serie	Class B, reinforced insulation Used for secondary wire	
			FURUKAWA ELECTRIC CO LTD	TEX-E	Class B, reinforced insulation Used for secondary wire	
			CHANGYUAN ELECTRONICS (SHENZHEN) CO LTD	CB-TIW	Reinforced insulation, rated 130° C (Class B)	
			SHENZHEN JIUDING NEW MATERIAL CO LTD	DTIW-B	Class B	
			TOTOKU ELECTRIC CO LTD	TIW-2X	Min.130°C	
			E&B TECHNOLOGY CO LTD	E&B-XXXB	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]
14	13	Bobbin	CHANG CHUN PLASTICS CO LTD	T375J	V-0, 150°C, thickness 0,45 mm min.	cURus
				T375HF		
			SUMITOMO BAKELITE CO LTD	PM-9820	V-0, 150°C, thickness 0,45 mm min.	
			Chang Chun Plastics	PBT--4130	Rated: V¬0 at min. 0,74 mm thickness; min. 140°C	
			HITACHI CHEMICAL CO LTD	CP-J-8800	V-0, 150°C, thickness 0,45 mm min.	
15	14	Insulating tape	3M COMPANY ELECTRICAL MARKETS DIV (EMD)	1350F-1(b)	Min.130°C (b) - May be marked "Comparative Tracking Index (CTI)) equal to or greater than 400V but less than 600V, PLC=1, UL840 Material Group II, when tested to IEC60112 on both sides of tape"	cURus
				1350T-1		
				44		
			BONDTEC PACIFIC CO LTD	370S(b)		
			JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CO LTD	PZ*(b)	Min.130°C (b) - Comparative Tracking Index (CTI) performance indicates material Group IIIa, PLC=2, CTI equal to or greater than 250 but less than 400 v. (c) - Comparative Tracking Index (CTI) performance indicates material Group I, PLC=0, CTI equal to or greater than 600 v. (g) - The CTI test was conducted per IEC 112, 3rd Edition 1979 and the assigned level is based on the testing of both film and adhesive sides. * - May be followed by suffixes	
				CT*(c)(g)		
				CT(b)(g)		
			JINGJIANG JINGYI ADHESIVE PRODUCT CO LTD	JY25-A(b)	Min.130°C (b) - May be marked "Film side" CTI 600-3.0 in White color, and CTI 175-3.0 in other colors mm per IEC 60112, Fourth Edition (2003) CTI Material and "Adhesive side" CTI 600-3.0 in white color, and CTI 175-3.0mm in other colors per IEC 60112, Fourth Edition (2003) CTI Material or equivalent.	
			CHANG SHU LIANG YI TAPE INDUSTRY CO LTD	LY-XX	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]
15	15 (not shown)	Mylar Insulating Sheet	TORAY INDUSTRIES INC	Lumirror H10	VTM-2, min. 0.4 mm thickness, 105°C	cURus
			SKC CO LTD	SH71S	VTM-2, min. 0.4 mm thickness,	
			FORMEX, DIV OF ILLINOIS TOOL WORKS INC, FORMERLY	FORMEX GK	V-0, min. 0.4 mm thickness, 105°C	
			SABIC INNOVATIVE PLASTICS US L L C	FR60 series	V-0, min. 0.4 mm thickness, 105°C	
				FR63 series		
				FR65 series		
				FR700series		
				FR7 series		
			CHENGDU KANGLONGXIN PLASTICS CO LTD	KLX PP WT-10 series	VTM-0, min. 0.4 mm thickness, 105°C	
			MIAN YANG	PP-(i)(j)	VTM-0, min. 0.4 mm thickness, 105°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]
16, 17	16	Power Supply cord	YUNG LI CO LTD	SVT	Min.18AWG, 105°C, VW-1, with or without Hospital Grade USA Plug or Regular Use USA Plug, NEMA 5-15P	cURus
			JHI WEI ELECTRIC WIRE & CABLE CO LTD	SVT	Min.18AWG, 105°C, VW-1, with or without Hospital Grade USA Plug or Regular Use USA Plug, NEMA 5-15P	
			I SHENG ELECTRONICS (KUNSHAN) CO LTD	SVT	Min.18AWG, 105°C, VW-1, with or without Hospital Grade USA Plug or Regular Use USA Plug, NEMA 5-15P	
16, 17	17	Output Cord	SUZHOU YEMAO ELECTRONIC CO LTD	1185 2464 2468	Min. 24AWG, min. 300Vac, min. 80°C	cURus
			ZHUANG SHAN CHUAN ELECTRICAL PRODUCTS (KUNSHAN) CO LTD	Various	Min. 24AWG, min. 300Vac, min. 80°C	
			SUZHOU LIQIN ELECTRONICS CO LTD	Various	Min. 24AWG, min. 300Vac, min. 80°C	
			SUZHOU DIOUDE ELECTRONICS CO LTD	Various	Min. 24AWG, min. 300Vac, min. 80°C	
8	18 (not shown)	Earthing wire	KUNSHAN NEW ZHICHENG ELECTRONICS TECHNOLOGIE S CO LTD	1015 1007 1185	Min. 20 AWG, Min. 300V, Min. 80°C	cURus
			ZHUANG SHAN CHUAN ELECTRICAL PRODUCTS (KUNSHAN) CO LTD	1015 1007 1185	Min. 20 AWG, Min. 300V, Min. 80°C	
			YONG HAO ELECTRICAL INDUSTRY CO LTD	1015 1007 1185	Min. 20 AWG, Min. 300V, Min. 80°C	
			KUNSHAN XINGHONGMEN G ELECTRONIC CO LTD	1015 1007 1185	Min. 20 AWG, Min. 300V, Min. 80°C	
			SUZHOU YEMAO ELECTRONIC CO LTD	1015 1007 1185	Min. 20 AWG, Min. 300V, Min. 80°C	
			SHENG YU ENTERPRISE CO LTD	1015 1007 1185	Min. 20 AWG, Min. 300V, Min. 80°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]
1	19 (not shown)	Label	FAN JA PAPER PRINTING CO LTD	FJ-03-3	Rated min 80 deg C. Suitable for use on the plastic enclosure. (Optional)	cURus
			FAN JA PAPER PRINTING CO LTD	FJ07	Rated min 80 deg C. Suitable for use on the plastic enclosure. (Optional)	
			E-LIN ADHESIVE LABEL CO LTD	EL-15	Rated min 80 deg C. Suitable for use on the plastic enclosure. (Optional)	
			SUZHOU HAIRONG PACKING PRODUCTION CO LTD	HR-01 HR-02	Rated min 80 deg C. Suitable for use on the plastic enclosure. (Optional)	
			STEVEN LABEL CORP	HW332RL	Rated min 80 deg C. Suitable for use on the plastic enclosure. (Optional)	
			FAN JA PAPER PRINTING CO LTD	FJ-03-3	Rated min 80 deg C. Suitable for use on the plastic enclosure. (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]
10, 11, 12, 13	20	PCB	WALEX ELECTRONIC (WUXI) CO LTD	T2 T2A T2B T4	Min. 1,6 mm thickness, min. V-0, 130°C	cURus
			YUANMAN PRINTED CIRCUIT CO LTD	1V0	Min. 1,6 mm thickness, min. V-0, 130°C	
			SUZHOU XINKE ELECTRONICS CO LTD	XK-2 XK1	Min. 1,6 mm thickness, min. V-0, 130°C	
			DONGGUAN HE TONG ELECTRONICS CO LTD	CEM1 2V0 FR4	Min. 1,6 mm thickness, min. V-0, 130°C	
			KUNSHAN CITY HUA SHENG CIRCUIT BOARD CO LTD	HS-S	Min. 1,6 mm thickness, min. V-0, 130°C	
			CHEERFUL ELECTRONIC	02 03 03A	Min. 1,6 mm thickness, min. V-0, 130°C	
			JIANGSU DIFEIDA ELECTRONICS	DFD-1	Min. 1,6 mm thickness, min. V-0, 130°C	
			DONGGUAN DAYSUN ELECTRONIC CO LTD	DS2	Min. 1,6 mm thickness, min. V-0, 130°C	
			SUZHOU CITY YILIHUA ELECTRONICS CO LTD	YLH-1	Min. 1,6 mm thickness, min. V-0, 130°C	
			DAFENG AREX ELECTRONICS TECHNOLOGY CO LTD	02V0 04V0 03V0	Min. 1,6 mm thickness, min. V-0, 130°C	
			BRITE PLUS ELECTRONICS (SUZHOU) CO LTD	DKV0-3A DGV0-3A	Min. 1,6 mm thickness, min. V-0, 130°C	
			KUOTIANG ENT LTD	C-2 C-2A	Min. V-0, min 1.6 mm thickness, 130°C	
			PACIFIC WIN INDUSTRIAL LTD	PW-02 PW-03	Min. V-0, min 1.6 mm thickness, 130°C	
			SHENZHEN TONGCHUANGXIN ELECTRONICS CO LTD	TCX	Min. 1,6 mm thickness, min. V-0, 130°C	
			SHANGHAI H-FAST ELECTRONICS CO LTD	211001	Min. 1,6 mm thickness, 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]
17	21	Mains Plug	YUNG LI CO LTD	YP-18	Min.125V 15A	cURus
			JHI WEI ELECTRIC WIRE	JW-05		
				JW-07		
			SELF-MAN INDUSTRIAL CO	SM-045		

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 - All uninsulated live parts in primary circuitry are housed within a non-metallic enclosure constructed with no openings.
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 primary wiring is minimum 20AWG, with a minimum rating of 300V, 80°C
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 11) was constructed as indicated in Illustrations 6 to 8c. These records must be available at the factory for inspection on every received shipment.

7.0 Illustrations

Illustration 1 - Model list

Model	Input	Output voltage (Vdc)	Output current (A)	Max. output power (W)
GT*961600P**-T2/T2A/T3/T3A/TW/TP* GT*961800P**-T2/T2A/T3/T3A/TW/TP*	100-240V~, 50-60Hz, 2.2A	12-14.9Vdc	13.33A	160W
GT*961600P**-T2/T2A/T3/T3A/TW/TP* GT*961800P**-T2/T2A/T3/T3A/TW/TP*		15-18.9Vdc	11.33A	170W
GT*961600P**-T2/T2A/T3/T3A/TW/TP* GT*961800P**-T2/T2A/T3/T3A/TW/TP*		19-54Vdc	9.47A	180W

7.0 Illustrations

Illustration 2 - Insulation diagram

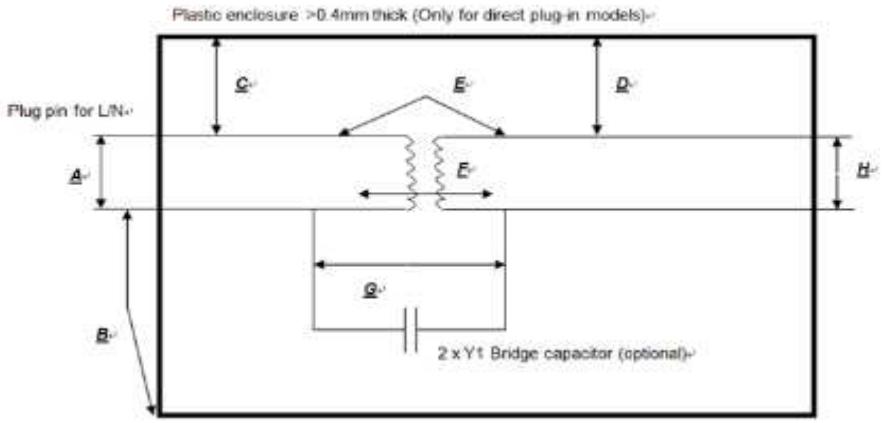


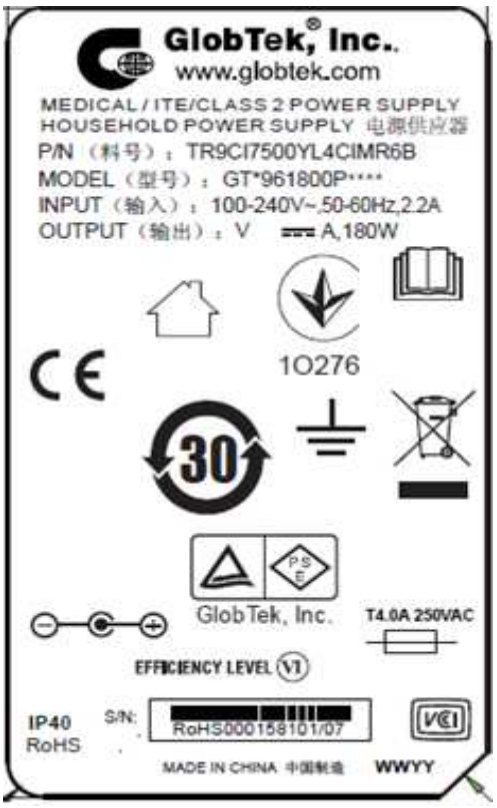
TABLE: INSULATION DIAGRAM		P
Pollution degree .....:	2	—
Overvoltage category.....:	II	—
Altitude.....:	Up to 5000m, use multiple factor 1.29 for MOPP, multiple factor 1.48 for MOOP	—
Additional details on parts considered as applied parts .....:	☒ None ☐ Areas _____ (See Clause 4.6 for details)	—

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	1MOOP	IIIb	240	--	2.96	2.96	4.1	4.1	Mains opposite polarity
B	2MOPP	IIIb	240	--	8.0	6.45	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	6.45	8.8	8.8	Mains to secondary on PCB
F	2MOPP	IIIb	240	352	8.0	6.45	12.4	12.4	Mains to secondary on transformer
G	2MOPP	IIIb	240	352	8.0	6.45	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.



RECOGNIZED COMPONENT
C ETL US
Intertek
4007497

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

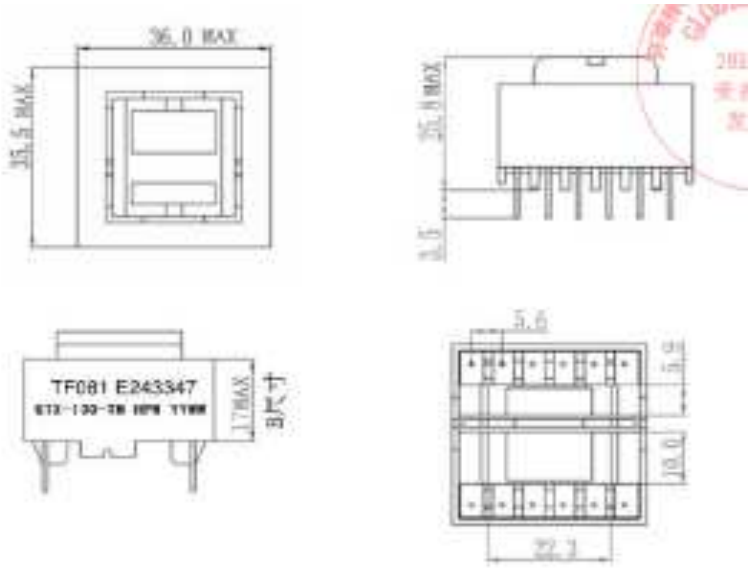
7.0 Illustrations

Illustration 6 - Ratings of Transformer

Model	Input	)utput
TF081	100-240Vac	12V-14.9V
TF082		13.4V-14.9V
TF083		15V-18.9V
TF084		17V-18.9V
TF085		19V-23.9V
TF086		21.5V-23.9V
TF087		24V-31.9V
TF088		27.6V-31.9V
TF089		32V-41.9V
TF090		36.5V-41.9V
TF091		42V-47.9V
TF092		48V-54V

7.0 Illustrations

Illustration 7 - Specifications for Transformer



7.0 Illustrations

Illustration 8 - Winding specificaiton for Transformer

TF081:

NO	TERMINAL		TS	WIRE	STDS	INSULATION MATERIAL	INSULATION LAYERS	BARRIER TAPE
	S	F						
N1	9		6	TRWB Φ0.20	2	PET TAPE 25u	6.5 × 1T	
N2	7	8	34	多股线 Φ0.10	20	PET TAPE 25u	6.5 × 3T	
N3	9		6	TRWB Φ0.20	2	PET TAPE 25u	6.5 × 1T	
N4	1	4	2	多股线 Φ0.10*80	2	PET TAPE 25u	10.5 × 1T	3 × 1T
N5	3	2	2	多股线 Φ0.10*80	2	PET TAPE 25u	10.5 × 1T	3 × 1T
N6	10	9	3	TRWB Φ0.20	2	PET TAPE 25u	10.5 × 2T	
N7	9	11	3	TRWB Φ0.20	2			
N8						PET TAPE 25u	6.5 × 2T	

TF083:

顺序 Order	PIN 脚 PIN No.	铜线 Copper wire	圈数 Turns	线槽 Slot	方向 Direction	备注 Remarks
E1	9--	TIW wire "0.2mm"2	6Ts	Gap A	Finish unterminated	
1 Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
P1	7-8	Litz wire 0.1mm"20	42Ts	Gap A		4 layers
1 Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
E2	9--	TIW wire "0.2mm"2	6Ts	Gap A	Finish unterminated	
1 Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
S1A	1-4	Litz wire 0.1mm*60 2PCS	3Ts	GAP B	Space winding near center	
S1B	3-2	Litz wire 0.1mm*60 2PCS	3Ts	GAP B	Space winding near center	
1 Ts W=9.5mm, T=0.025mm insulation tape @Gap B						
P2A	10-9	TIW wire 0.2mm"2	4Ts	Gap B	Winding together	
P2B	9-11	TIW wire 0.2mm"2	4Ts	Gap B		
2Ts W=9.5mm, T=0.025mm insulation tape @Gap B						
2Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
Adding the bobbin cover.						
2Turns W=11mm T=0.025mm core fixing tape						

TF084:

顺序 Order	PIN 脚 PIN No.	铜线 Copper wire	圈数 Turns	线槽 Slot	方向 Direction	备注 Remarks
E1	9--	TIW wire "0.2mm"2	6Ts	Gap A	Finish unterminated	
1 Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
P1	7-8	Litz wire 0.1mm"20	36Ts	Gap A		4 layers
1 Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
E2	9--	TIW wire "0.2mm"2	6Ts	Gap A	Finish unterminated	
1 Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
S1A	1-4	Litz wire 0.1mm*60 2PCS	3Ts	GAP B	Space winding near center	
S1B	3-2	Litz wire 0.1mm*60 2PCS	3Ts	GAP B	Space winding near center	
1 Ts W=9.5mm, T=0.025mm insulation tape @Gap B						
P2A	10-9	TIW wire 0.2mm"2	4Ts	Gap B	Winding together	
P2B	9-11	TIW wire 0.2mm"2	4Ts	Gap B		
2Ts W=9.5mm, T=0.025mm insulation tape @Gap B						
2Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
Adding the bobbin cover.						
2Turns W=11mm T=0.025mm core fixing tape						

7.0 Illustrations

Illustration 8a - Winding specificaiton for Transformer

TF085:

顺序 Order	PIN 脚 PIN No.	铜线 Copper wire	圈数 Turns	线槽 Slot	方向 Direction	备注 Remarks
E1	9--	TIW wire *0.2mm*2	6Ts	Gap A	Finish unterminated	
1 Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
P1	7-8	Litz wire 0.1mm*20	32Ts	Gap A		4 layers
1 Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
E2	9--	TIW wire *0.2mm*2	6Ts	Gap A	Finish unterminated	
1 Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
S1A	1-4	Litz wire 0.1mm*80	3Ts	Gap B	Space winding near central	
S1B	3-2	Litz wire 0.1mm*80	3Ts	Gap B	Space winding near central	
1 Ts W=9.5mm, T=0.025mm insulation tape @Gap B						
P2A	10-9	TIW wire 0.2mm*2	3Ts	Gap B	Winding together	
P2B	9-11	TIW wire 0.2mm*2	3Ts	Gap B		
2Ts W=9.5mm, T=0.025mm insulation tape @Gap B						
2Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
Adding the bobbin cover.						
2Turns W=11mm T=0.025mm core fixing tape						

TF086:

顺序 Order	PIN 脚 PIN No.	铜线 Copper wire	圈数 Turns	线槽 Slot	方向 Direction	备注 Remarks
E1	9--	TIW wire *0.2mm*2	6Ts	Gap A	Finish unterminated	
1 Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
P1	7-8	Litz wire 0.1mm*20	38Ts	Gap A		4 layers
1 Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
E2	9--	TIW wire *0.2mm*2	6Ts	Gap A	Finish unterminated	
1 Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
S1A	1-4	Litz wire 0.1mm*60	4Ts	Gap B	Space winding near central	
S1B	3-2	Litz wire 0.1mm*60	4Ts	Gap B	Space winding near central	
1 Ts W=9.5mm, T=0.025mm insulation tape @Gap B						
P2A	10-9	TIW wire 0.2mm*2	4Ts	Gap B	Winding together	
P2B	9-11	TIW wire 0.2mm*2	4Ts	Gap B		
2Ts W=9.5mm, T=0.025mm insulation tape @Gap B						
2Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
Adding the bobbin cover.						
2Turns W=11mm T=0.025mm core fixing tape						

TF088:

顺序 Order	PIN 脚 PIN No.	铜线 Copper wire	圈数 Turns	线槽 Slot	方向 Direction	备注 Remarks
E1	9--	TIW wire *0.2mm*2	6Ts	Gap A	Finish unterminated	
1 Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
P1	7-8	Litz wire 0.1mm*20	37Ts	Gap A		4 layers
1 Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
E2	9--	TIW wire *0.2mm*2	6Ts	Gap A	Finish unterminated	
1 Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
S1A	1-4	Litz wire 0.1mm*50	5Ts	Gap B	Space winding near central	
S1B	3-2	Litz wire 0.1mm*50	5Ts	Gap B	Space winding near central	
1 Ts W=9.5mm, T=0.025mm insulation tape @Gap B						
P2A	10-9	TIW wire 0.2mm*2	4Ts	Gap B	Winding together	
P2B	9-11	TIW wire 0.2mm*2	4Ts	Gap B		
2Ts W=9.5mm, T=0.025mm insulation tape @Gap B						
2Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
Adding the bobbin cover.						
2Turns W=11mm T=0.025mm core fixing tape						

7.0 Illustrations

Illustration 8b - Winding specificaiton for Transformer

TF089:

顺序 Order	PIN 脚 PIN No.	铜线 Copper wire	圈数 Turns	线槽 Slot	方向 Direction	备注 Remarks
E1	9--	TIW wire *0.2mm*2	6Ts	Gap A	Finish unterminated	
1 Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
P1	7-8	Litz wire 0.1mm*20	32Ts	Gap A		4 layers
1 Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
E2	9--	TIW wire *0.2mm*2	6Ts	Gap A	Finish unterminated	
1 Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
S1A	1-4	Litz wire 0.1mm*40	5Ts	Gap B	Space winding near center	
S1B	3-2	Litz wire 0.1mm*40	5Ts	Gap B	Space winding near center	
1 Ts W=9.5mm, T=0.025mm insulation tape @Gap B						
P2A	10-9	TIW wire 0.2mm*2	3Ts	Gap B	Winding together	
P2B	9-11	TIW wire 0.2mm*2	3Ts	Gap B		
2Ts W=9.5mm, T=0.025mm insulation tape @Gap B						
2Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
Adding the bobbin cover.						
2Turns W=11mm T=0.025mm core fixing tape						

TF090:

顺序 Order	PIN 脚 PIN No.	铜线 Copper wire	圈数 Turns	线槽 Slot	方向 Direction	备注 Remarks
E1	9--	TIW wire *0.2mm*2	6Ts	Gap A	Finish unterminated	
1 Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
P1	7-8	Litz wire 0.1mm*20	33Ts	Gap A		4 layers
1 Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
E2	9--	TIW wire *0.2mm*2	6Ts	Gap A	Finish unterminated	
1 Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
S1A	1-4	Litz wire 0.1mm*30	6Ts	Gap B	Space winding near center	
S1B	3-2	Litz wire 0.1mm*30	6Ts	Gap B	Space winding near center	
1 Ts W=9.5mm, T=0.025mm insulation tape @Gap B						
P2A	10-9	TIW wire 0.2mm*2	3Ts	Gap B	Winding together	
P2B	9-11	TIW wire 0.2mm*2	3Ts	Gap B		
2Ts W=9.5mm, T=0.025mm insulation tape @Gap B						
2Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
Adding the bobbin cover.						
2Turns W=11mm T=0.025mm core fixing tape						

TF091:

顺序 Order	PIN 脚 PIN No.	铜线 Copper wire	圈数 Turns	线槽 Slot	方向 Direction	备注 Remarks
E1	9--	TIW wire *0.2mm*2	6Ts	Gap A	Finish unterminated	
1 Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
P1	7-8	Litz wire 0.1mm*20	34Ts	Gap A		4 layers
1 Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
E2	9--	TIW wire *0.2mm*2	6Ts	Gap A	Finish unterminated	
1 Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
S1A	1-4	Litz wire 0.1mm*30	7Ts	Gap B	Space winding near center	
S1B	3-2	Litz wire 0.1mm*30	7Ts	Gap B	Space winding near center	
1 Ts W=9.5mm, T=0.025mm insulation tape @Gap B						
P2A	10-9	TIW wire 0.2mm*2	3Ts	Gap B	Winding together	
P2B	9-11	TIW wire 0.2mm*2	3Ts	Gap B		
2Ts W=9.5mm, T=0.025mm insulation tape @Gap B						
2Ts W=5.5mm, T=0.025mm insulation tape @Gap A						
Adding the bobbin cover.						
2Turns W=11mm T=0.025mm core fixing tape						

7.0 Illustrations

Illustration 8c - Winding specificaiton for Transformer

顺序 Order	PIN 脚 PIN No.	铜线 Copper wire	圈数 Turns	线槽 Slot	方向 Direction	备注 Remarks
E1	9--	TIW wire *0.2mm*2	6Ts	Gap A	Finish unterminated	
1 Ts W=5.5mm, T=0.025mm Insulation tape @Gap A						
P1	7-8	Litz wire 0.1mm*20	34Ts	Gap A		4 layers
1 Ts W=5.5mm, T=0.025mm Insulation tape @Gap A						
E2	9--	TIW wire *0.2mm*2	6Ts	Gap A	Finish unterminated	
1 Ts W=5.5mm, T=0.025mm Insulation tape @Gap A						
S1A	1-4	Litz wire 0.1mm*25	8Ts	Gap B	Space winding near cente	
S1B	3-2	Litz wire 0.1mm*25	8Ts	Gap B	Space winding near cente	
1 Ts W=9.5mm, T=0.025mm Insulation tape @Gap B						
P2A	10-9	TIW wire 0.2mm*2	3Ts	Gap B	Winding together	
P2B	9-11	TIW wire 0.2mm*2	3Ts	Gap B		
2Ts W=9.5mm, T=0.025mm Insulation tape @Gap B						
2Ts W=5.5mm, T=0.025mm Insulation tape @Gap A						
Adding the bobbin cover.						
2Turns W=11mm T=0.025mm core fixing tape						

8.0 Test Summary						
Evaluation Period	2018-04-16 to 2018-05-15				Project No.	180401376SHA
Sample Rec. Date	16-Apr-2018	Condition	Prototype		Sample ID.	0180529-09
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

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			
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:	Larry Zhong	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
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:

Product - 100% of production of the products covered by this Report	**Test Voltage**	**Test Time**
All the product covered by this report Between mains part and secondary circuits	4000Vac	1 s
Product - Transformer of Section 4.0 item 11	**Test Voltage**	**Test Time**
Between prim. and sec. output	4000Vac	1 min
Between prim. and core	1500Vac	1 min

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
				None