

RECOGNIZED COMPONENT Constructional Data Report (CDR)

1.0 Reference and Address							
Report Number	210600861SHA-001 Original Issu	ed: 7-Sep-2021	Revised: None				
	Performance [AAMI ES60601-1:200	95+A1]	nents For Basic Safety And Essential				
	Medical Electrical Equipment - Part Performance (R2018) [CSA C22.2#		nents for Basic Safety and Essential				
	Medical Electrical Equipment – Par Performance – Collateral Standard:		rements for Basic Safety and Essential 1-1-6:2010 Ed.3+A1;A2]				
Standard(s)			ements for Basic Safety and Essential SA C22.2#60601-1-6:2011 Ed.3+A1]				
	Medical Electrical Equipment – Part 1–11: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment [IEC 60601-1-11:2015 Ed.2+A1]						
	Performance - Collateral Standard:	Requirements for M	irements for Basic Safety and Essential edical Electrical Equipment and Medical onment [CSA C22.2#60601-1-11:2015				
Entirely Replace	ces Report Number 180401376SH						
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2.0 Product Description Medical Power Supply Product GlobTek Brand name 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. Description 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. 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. Models 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. 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 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"*" Model Similarity =-T2 means desktop class II with C8 AC inlet =-T2A means desktop class II with C18 AC inlet =-T3 means desktop class I or class II with functional earth with C14 AC inlet =-T3A means desktop class I or class II with functional earth 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. Input: 100-240V~, 50-60Hz or 50/60Hz, 2,2A: Output: 12-54VDC, Max.13.33A, Max. 180W Ratings (Refer to illustration No.1 for details.) Other Ratings NA

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150KVA.

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. Scope of Power Supply evaluation defers the following clauses to be determined as part of the end product investigation: Conditions of Clause 7.5 (Safety Signs), Acceptability 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

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Photo 1 - External view of EUT



Photo 2 - External view of EUT



Photo 3 - Internal view with Top Enclosure Removed

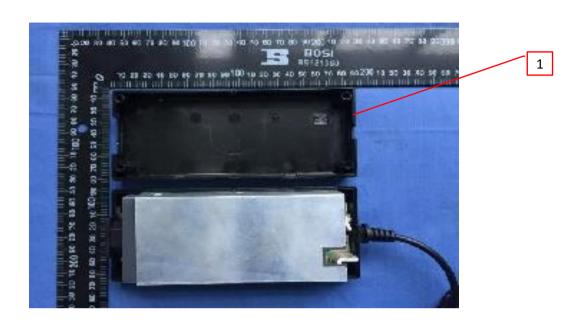


Photo 4 - Internal view with Lower Enclosure Removed

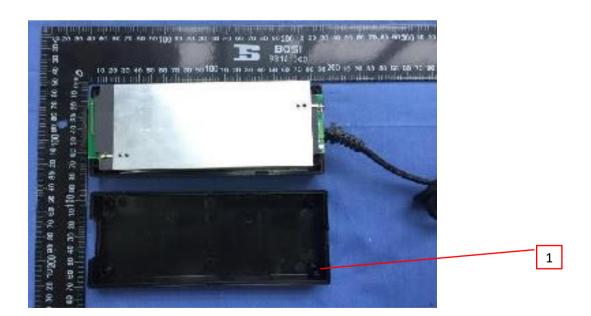


Photo 5 - Internal view with Top Metal Cover Removed

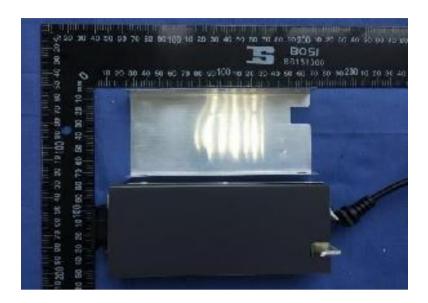


Photo 6 - Internal view with Lower Metal Cover Removed

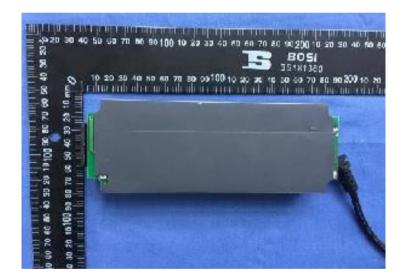


Photo 7 - Internal view with Insulation Sheet Removed



Photo 8 - PCB Top Side (Class I)

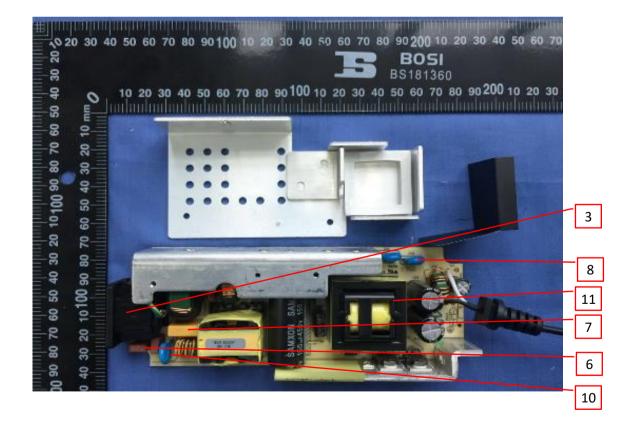


Photo 9 - PCB Top Side (Class II)

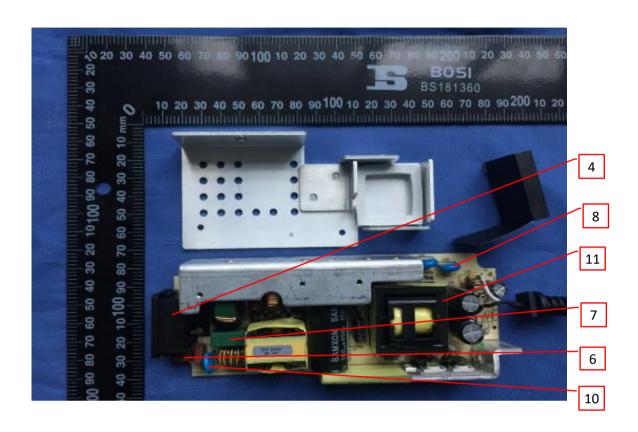


Photo 10 - PCB Bottom Side(12.0-36.0V model, Class I)

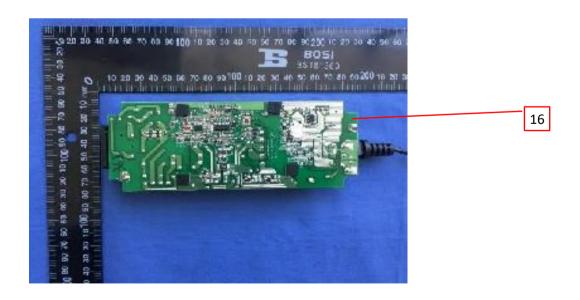


Photo 11 - Bottom Side(36.1-54V model, Class I)

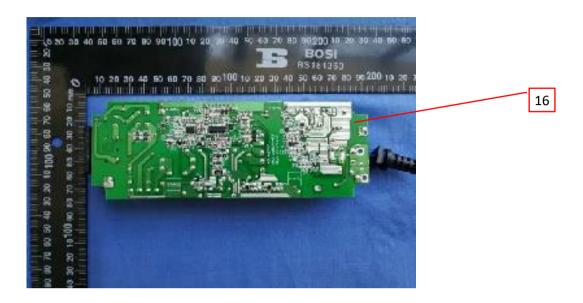


Photo 12 - PCB Bottom Side(12.0-36.0V model, Class II)



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

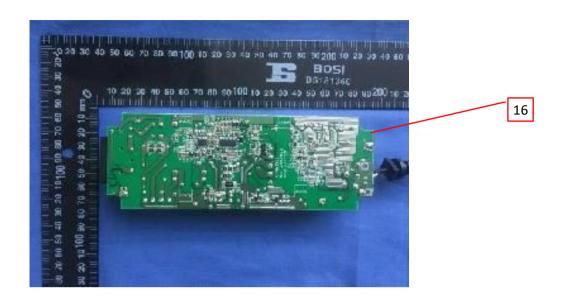


Photo 14 - External view of transformer

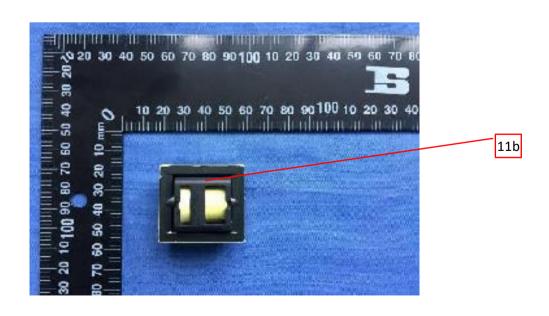


Photo 15 - Internal view of transformer

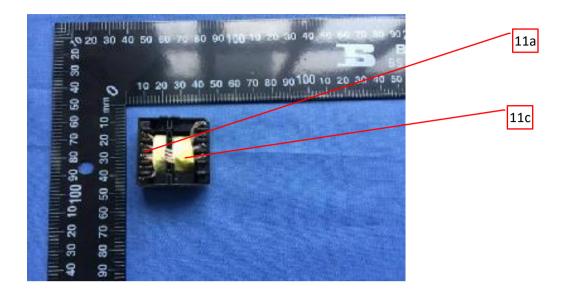
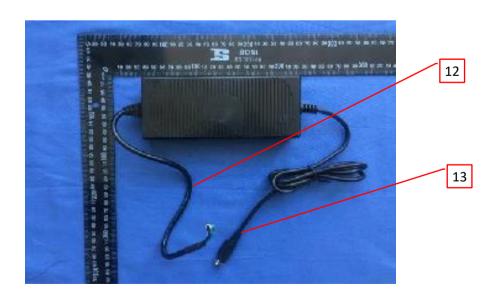


Photo 16 - Cord Connected Model Without Plug



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Photo 17 - Cord Connected Model With Plug



Photo 18 - PCB top view (earth part optional 2)



Photo 19 - PCB top view (earth part optional 1)

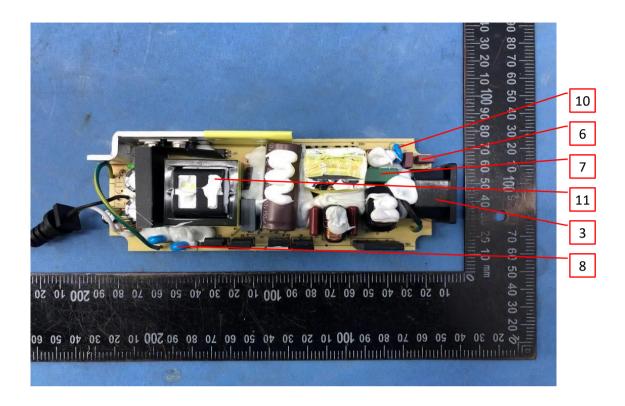
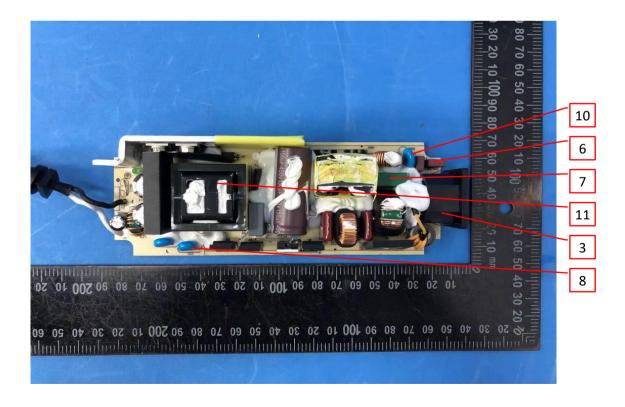


Photo 20 - PCB top view (earth part optional 3)



	.0 Critical Components								
Photo #	Item no.1	Name	Manufacturer/ trademark ²	Type / model ²	Technical data and securement means	Mark(s) of conformity			
			SABIC INNOVATIVE PLASTICS	SE1X SE1 SE100 HF500R CX7211 EXCY0098 C2950 945	Min.V-1, min. 2.0mm thickness, 105°C				
1,2, 3,4	1	Enclosure	SABIC JAPAN L L C TEIJIN	CX7211 C2950 945 LN-1250P	Min.V-1, min. 2.0mm thickness, 105°C Min. V-0 at 1,5 mm thickness,	cURus			
						CHEMICALS LTD COVESTRO DEUTSCHLAND AG [PC RESINS] Various	LN-1250G 6485 Various	Min. V-0 at 1,5 mm thickness, 115°C Min. V-1, min.1.5 mm thickness, 105°C	
8	2	CN1 Class I units C6 type Appliance inlet (not shown)	Technology Co Ltd Inalways Corp. Zhe Jiang Bei Er jia Rong Feng Industrial Co., Ltd.	DB6 TU333 R30790 S02 CDJ2 724 ST-A04-002 RF-190	250 Vac; 2,5A; 3 pins, 75°C 250 Vac; 2,5A; 3 pins 250 Vac; 2,5A; 3 pins	cURus			
8, 18, 19, 20	3	CN1 Class I units C14 type Appliance inlet	Zhejiang LECI Electronics TecxUnions Technology Corp Rich Bay Co Ltd Sun Fair Electric Wire & Cable (HK) Co Ltd Inalways Corp. Zhe Jiang Bei Er jia Rong Feng Industrial Co., Ltd.	DB14 TU-301-S TU-301-SP R-301SN SS-120 711 ST-A01-003J SS-120	250 Vac; 10A; 3 pins	cURus			

GlobTek, Inc.

4.0 Critical Components Mark(s) of Item Manufacturer/ Technical data and securement conformity Name Type / model² no.1 trademark² means # Zhejiang LECI DB--8 250 Vac; 2,5A; 2 pins **Electronics** Delikang Electronics CDJ--8 250 Vac; 2,5A; 2 pins Technology Co Ltd Rich Bay Co Ltd R-201SN90 250 Vac; 2,5A; 2 pins Sun Fair Electric CN1 Class II units Wire & Cable (HK) S--01 250 Vac; 2,5A; 2 pins C8 type Appliance cURus 9 4 Co Ltd inlet **Tecx-unions** SO--222 series 250 Vac; 2,5A; 2 pins Technology Corp Inalways Corp. 721 250 Vac; 2,5A; 2 pins Zhe Jiang Bei Er ST-A03-005 250 Vac; 2,5A; 2 pins jia Rong Feng RF-180 2,5A, 250Vac Industrial Co., Ltd. Rong Feng CN1 Class II SS-120A 10A,250V Industrial Co..Ltd units C18 9 cURus type Appliance **RICH BAY CO** R-301SN 10A,250V inlet (not shown) LTD Conquer Electronics Co., MST series Ltd. Ever Island Electric Co., Ltd. 2010 And Walter Electric Zhongshan Lanbao Electrical RTI--10 **Appliances** 8,9, 18, Bel Fuse Ltd. T4A, 250V RST Serie Fuse 6 cURus 19, (F1,F2), F2 is optional Cooper SS-5 20 Bussmann LLC Dongguan Better 932 Cooper SS-5 Bussmann Inc. Shenzhen Lanson SMT Electronics Conquer Electronics Co., **MET** Ltd. Max 0.47µF, Min.300V,105°C Cheng Tung CTX X1 or X2 Industrial Co., Ltd. (CX1) Max 0.47μF, Min.250V,100°C Tenta Electric MEX X1 or X2 Industrial Co. Ltd. (CX1) Max 0.47μF, Min.300V,110°C Joey **MPX** X1 or X2 (CX1) Ultra Tech Xiphi Max 0.47µF, Min.250V,110°C Enterprise Co. HQX X2 Ltd. (CX1)

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	Critic	al Components				
Photo #	Item no.1	Name	Manufacturer/ trademark ²	Type / model ²	Technical data and securement means	Mark(s) of conformity
8,9,			YUON YU ELECTRONICS CO LTD	MPX	Max 0.47μF, Min.250V,100°C Χ2 (CX1)	
18, 19, 20	9,	X capacitor	SINHUA ELECTRONICS (HUZHOU) CO LTD	MPX	Max 0.47μF, Min.300V,110°C X1 or X2 (CX1)	cURus
			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.		Max 0.47μF, Min.250V,110°C X2 (CX1)	
			Various	Various	Max 0.47μF, Min.250V,100°C X1 or X2 (CX1)	
			TDK-EPC Corporation, Capacitors Group Circuit Devices Business Group	CD	Min. 250Vac; max. 2200pF; min. Y1 (CY1,CY2) (CY2, Optional)	
			Success Electronics Co.,	SE	Min. 250Vac; max. 2200pF; min. Y1	
			Ltd.	SB	(CY1,CY2) (CY2, Optional)	
			Walsin Technology Corp.	АН	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)	
8,9, 18, 19,	8	Y capacitor	JYH CHUNG ELECTRONICS CO LTD	JD	Min.400Vac; max. 2200pF; min. Y1 (CY1,CY2) (CY2, Optional)	cURus
20			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)	

4.0	0 Critical Components							
Photo #	Item no.1	Name	Manufacturer/ trademark ²	Type / model ²	Technical data and securement means	Mark(s) of conformity		
			WELSON INDUSTRIAL CO LT D	WD	Min. 250Vac; max. 2200pF; min. Y1 (CY1,CY2) (CY2, Optional) Min. 250Vac; max. 2200pF; min.			
			Various	Various	Y1 (CY1,CY2) (CY2, Optional)			
			Everlight Electronics Co., Ltd.	EL817	Dti=0.5mm Int. dcr=6.0mm EXT.dcr=7.7mm,thermal cycling test,110°C (U4)			
			COSMO Electronics Corporation	K1010	Dti=0.6mm Int. dcr=4.0mm,			
				KP1010	Ext.dcr=5.0mm,thermal cycling test,115°C (U4)			
	9 Photo Coupler (not shown)	Lite-On Technology Corporation	LTV-817	Dti=0.8mm EXT. dcr=7.8mm,thermal cycling test,110°C (U4)				
8			Fairchild Semiconductor Ltd	H11A817B	Insulation voltage: 850V; Transient overvoltage: 6000V; CTI175; Int. Cr/ Ext. Cr: ≥7,0/ 7,0 mm; 30/110/21	cURus		
		(not snown)	Sharp Corporation ElectronicCompon ents and Devices Group		(U4) Insulation voltage: 890V; Transient overvoltage: 9000V Int. Cr/ Ext. Cr: 7,62/ 7,62 mm; 30/110/21			
			Bright Led Electronics Corp.	BPC-817 A BPC-817 B BPC-817 C BPC-817 D BPC-817 L BPC-817MBPC- 817 S	(U4) Dti=0.4mm EXT. dcr=7.0mm,thermal cycling test,110°C (U4)			
			TOSHIBA	TLP781F	Dti> 0,4mm, Ext cr> 8,0mm, Isolation 3000Vac min., 110°C min., Thermal cycling test (U4)			
				TVR10471K	Max. Continuous voltage: min			
			TKS	TVR14471K	300Vac(rms), 105°C The coating is V-0 MOV1(optional)			
			Centra	CNR-10D471K	Max. Continuous voltage: min 300Vac(rms), 105C The coating is V-0 MOV1(optional)			
				CNR-14D471K	Max. Continuous voltage: min 300Vac(rms), 105C The coating is V-0 MOV1(optional)			

4.0	<u>Critic</u>	al Components					
Photo #	Item no.1	Name	Manufacturer/ trademark ²	Type / model ²	Technical data and securement means	Mark(s) of conformity	
			Success Electronics	SVR10D471K	Max. Continuous voltage: min 300Vac(rms), 105C		
			Co Ltd	SVR14D471K	The coating is V-0 MOV1(optional)		
			Walsin	VZ14D471K	Max. Continuous voltage: min 300Vac(rms), 85°C		
			VVaisiii	VZ10D471K	The coating is V-0 MOV1(optional)		
8,9,			Lien Shun Electronics Co.,	14D471K	Max. Continuous voltage: min 300Vac(rms), 105°C		
18, 19,	10	Varistor	Ltd.	10D471K	The coating is V-0 MOV1(optional)	cURus	
20			CERAMATE	GNR10D471K	Max. Continuous voltage: min 300Vac(rms), 105°C		
			021441111112	GNR14D471K	The coating is V-0 MOV1(optional)		
			Brightking	14D471K	Max. Continuous voltage: min 300Vac(rms), 105°C		
			<u> </u>	10D471K	The coating is V-0 MOV1(optional)		
			Joyin Co., Ltd.	10N471K	300V rms; 385V d.c., 3kA, 8/20μs 85°C		
		30yiii 30:, Eta:	14N471K	MOV1(optional)			
	SHANTOU HIGH- NEW TECHNOLOGY DEVELOPMNT		10D471K	Max. Continuous voltage: min 300Vac(rms), 105C			
			ZONE SONGTIAN ENTERPRISE CO LTD	14D471K	The coating is V-0 MOV1(optional)		
			Guangdong	V-471K-10D	Max. Continuous voltage: min		
			Huiwan Electronics	V-471K-10E	300Vac(rms), 105C		
			Technology Co	V-471K-14D	The coating is V-0 MOV1(optional)		
			Ltd	V-471-14E	iviO v i (optional)		
				TF081 TF082 TF083	Class D		
8,9, 18,	11	Transformer	GlobTek BOAM	TF084 TF085 TF086	Class B Ratings see illustration No(s). 6. Dimension see illustration No(s).	NR	
19, 20			Haopuwei	TF087 TF088	7. Winding specificaiton see		
				TF089 TF090 TF091 TF092	illustration No(s).8 to 8c.		
			Great Leoflon Industrial Co., Ltd.	TRW (B) Serie(s)	Class B, reinforced insulation Used for secondary wire (B) = Tinned copper		
			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		

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4.0	Critica	al Components				
Photo #	Item no.1	Name	Manufacturer/ trademark ²	Type / model ²	Technical data and securement means	Mark(s) of conformity
15	11a	Triple-insulated wire	CHANGYUAN ELECTRONICS (SHENZHEN) CO LTD	CB-TIW	Reinforced insulation, rated 130° C (Class B)	cURus
			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	
			CHANG CHUN	T375J	V-0, 150°C, thickness 0,45 mm	
	441	Debbin	PLASTICS CO SUMITOMO BAKELITE CO LTD	T375HF PM-9820	win. V-0, 150°C, thickness 0,45 mm min.	. LID
14	4 11b Bobbin	Chang Chun Plastics	PBT4130	Rated: V¬0 at min. 0,74 mm thickness; min. 140°C	cURus	
		HITACHI CHEMICAL CO LTD		CP-J-8800	V-0, 150°C, thickness 0,45 mm min.	
			3M COMPANY	1350F-1(b)	Min.130°C (b) - May be marked "Comparative	
			ELECTRICAL MARKETS DIV (EMD)	1350T-1	Tracking Index (CTI)) equal to or greater than 400V but less than	
			(CIVID)	44	600V, PLC=1, UL840 Material	
			BONDTEC PACIFIC CO LTD	370S(b)	Group II, when tested to IEC60112 on both sides of tape"	
		JINGJIANG YAHUA		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	
				CT*(c)(g)	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	
15	11c	Insulating tape		CT(b)(g)	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	cURus

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4.0 (0 Critical Components							
Photo #	Item no.1	Name	Manufacturer/ trademark ²	Type / model ²	Technical data and securement means	Mark(s) of conformity		
#			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			
			HUIZHOU YAHUA ELECTRONIC TECHNOLOGY CO LTD	СТ	Min.130°C			
			TORAY INDUSTRIES INC	Lumirror H10	VTM-2, min. 0.4 mm thickness, 105°C			
			SKC CO LTD	SH71S	VTM-2, min. 0.4 mm thickness, 105°C			
		Mylar d Insulating Sheet (not shown)	FORMEX, DIV OF ILLINOIS TOOL WORKS INC, FORMERLY	FORMEX GK	V-0, min. 0.4 mm thickness, 105°C			
15	11d		SABIC INNOVATIVE PLASTICS US L L C	FR60 series FR63 series FR65 series FR700series FR7 series	V-0, min. 0.4 mm thickness, 105°C	cURus		
			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			
			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			
16, 17	12	Power Supply cord (optional)	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	cURus		
			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			
			SUZHOU	1185	Min. 24AWG,			
			YEMAO ELECTRONIC	2464 2468	min. 300Vac, min. 80°C			

	Critic	al Components				
Photo #	Item no.1	Name	Manufacturer/ trademark ²	Type / model ²	Technical data and securement means	Mark(s) of conformity
16, 17	13	Output Cord	ZHUANG SHAN CHUAN ELECTRICAL PRODUCTS (KUNSHAN) CO LTD	Various	Min. 24AWG, min. 300Vac, min. 80°C	cURus
			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	
			KUNSHAN NEW	1015	Min. 20 AWG,	
			ZHICHENG	1007	Min. 300V, Min.	
			ELECTRONICS	1185	80°C	
			ZHUANG SHAN	1015	Min. 20 AWG,	
			CHUAN	1007	Min. 300V, Min.	
			ELECTRICAL	1185	80°C	
			YONG HAO	1015	Min. 20 AWG,]
			ELECTRICAL	1007	Min. 300V, Min.	
0	14	Earthing wire (not	INDUSTRY CO	1185	80°C	al IDa
8	14	shown)	KUNSHAN	1015	Min. 20 AWG,	cURus
		Jones Willy	XINGHONGMEN	1007	Min. 300V, Min.	
			G ELECTRONIC	1185	80°C	
			SUZHOU	1015	Min. 20 AWG,	1
			YEMAO	1007	Min. 300V, Min.	
			ELECTRONIC	1185	80°C	
			SHENG YU	1015	Min. 20 AWG,	†
			ENTERPRISE	1007	Min. 300V, Min.	
			COLTD	1185	80°C	
			FAN JA PAPER		Rated min 80 deg C. Suitable for	
			PRINTING CO LTD	FJ-03-3	use on the plastic enclosure. (Optional)	
			FAN JA PAPER PRINTING CO LTD	FJ07	Rated min 80 deg C. Suitable for use on the plastic enclosure. (Optional)	
1	15	Label (not shown)	E-LIN ADHESIVE LABEL CO LTD	EL-15	Rated min 80 deg C. Suitable for use on the plastic enclosure. (Optional)	cURus
			SUZHOU	HR-01	Rated min 80 deg C. Suitable for	
			HAIRONG	HR-02	use on the plastic enclosure.]
			STEVEN LABEL CORP	HW332RL	Rated min 80 deg C. Suitable for use on the plastic enclosure. (Optional)	
			FAN JA PAPER PRINTING CO	FJ-03-3	Rated min 80 deg C. Suitable for use on the plastic enclosure.	
			LTD		(Optional)	
			WALEX ELECTRONIC	T2 T2A T2B	Min. 1,6 mm thickness, min. V-0, 130°C	
			(WUXI) CO LTD	T4	1	
			YUANMAN PRINTED	1V0	Min. 1,6 mm thickness, min. V-0, 130°C	•
			CIRCUIT CO LTD SUZHOU XINKE	VK 2		-
			ELECTRONICS	XK-2 XK1	Min. 1,6 mm thickness, min. V-0, 130°C	
	I	I	LLLOTRONIOS	IVI I	130 0	1

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4.0 (Critic	al Components				
Photo #	Item no.1	Name	Manufacturer/ trademark ²	Type / model ²	Technical data and securement means	Mark(s) of conformity
			DONGGUAN HE TONG ELECTRONICS	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	
10,			JIANGSU DIFEIDA ELECTRONICS CO LTD	DFD-1	Min. 1,6 mm thickness, min. V-0, 130°C	
11, 12, 13	16	РСВ	DONGGUAN DAYSUN ELECTRONIC CO LTD	DS2	Min. 1,6 mm thickness, min. V-0, 130°C	cURus
		SUZHOU CITY YILIHUA ELECTRONICS CO LTD	YLH-1	Min. 1,6 mm thickness, min. V-0, 130°C		
			DAFENG AREX ELECTRONICS TECHNOLOGY	02V0 04V0 03V0	Min. 1,6 mm thickness, min. V-0, 130°C	
			BRITE PLUS ELECTRONICS	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 TONGCHUANGXI N ELECTRONICS CO LTD	тсх	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	
			YUNG LI CO LTD	YP-18	1	
17	17	Mains Plug	JHI WEI ELECTRIC WIRE	JW-05	 Min.125V 15A	cURus
.,	''	anio i iag	SELF-MAN	SM-045	Will. 120 V 10/1	331143
<u> </u>	<u> </u>		INDUSTRIAL CO		Į.	

NOTES

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¹⁾ Not all item numbers are indicated (called out) in the photos, as their location is obvious.

^{2) &}quot;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.

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5.0 Critical Unlisted CEC Components

No Unlisted CEC components are used in this report.

6.0 Critical Features

<u>Recognized Component</u> - A component part, which has been previously evaluated by an accredited certification body with restrictions and must be evaluated as part of the basic product considering the restrictions as specified by the Conditions of Acceptability.

<u>Listed Component</u> - A component part, which has been previously Listed or Certified by an accredited Certification Organization with no restrictions and is used in the intended application within its ratings.

<u>Unlisted Component</u> - A part that has not been previously evaluated to the appropriate designated component standard. It may also be a Listed or Recognized component that is being used outside of its evaluated Listing or component recognition.

<u>Critical Features/Components</u> - An essential part, material, subassembly, system, software, or accessory of a product that has a direct bearing on the product's conformance to applicable requirements of the product standard.

<u>Construction Details</u> - For specific construction details, reference should be made to the photographs and descriptions. All dimensions are approximate unless specified as exact or within a tolerance. In addition to the specific construction details described in this Report, the following general requirements also apply.

- 1. Spacing Refer to illustration No(s) 2, 2a, 2b and 2c for details.
- 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. <u>Corrosion Protection</u> 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. <u>Grounding</u> 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. <u>Internal Wiring</u> 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.
- 8. 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

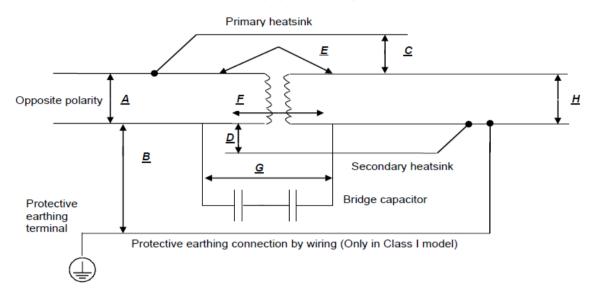
Model	Input	Output voltage (Vdc)	Output current (A)	Max. output power (W)
GT*961600P**-T2/T2A/T3/T3A/TW/TP* GT*961800P**-T2/T2A/T3/T3A/TW/TP*	100- 240V~.	12-14.9Vdc	13.33A	160W
GT*961600P**-T2/T2A/T3/T3A/TW/TP* GT*961800P**-T2/T2A/T3/T3A/TW/TP*	50-	15-18.9Vdc	11.33A	170W
GT*961600P**-T2/T2A/T3/T3A/TW/TP*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

7.0 Illustrations

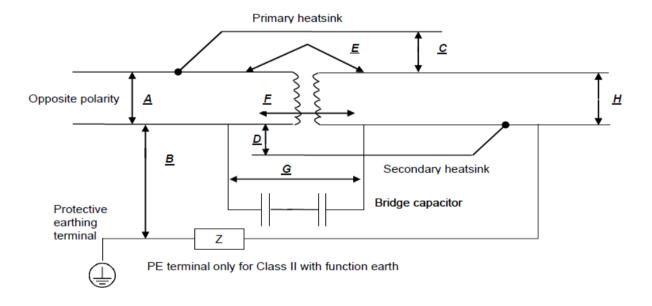
Illustration 2 - Spacings

INSULATION DIAGRAM

(E1) Earthed output



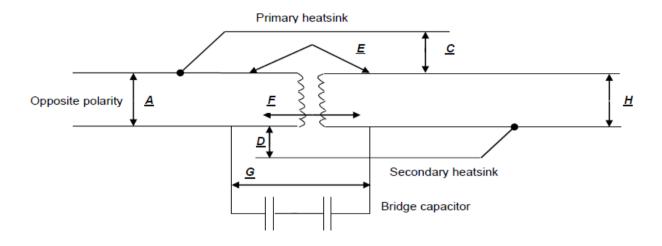
(E2) Class II, FE, Earthed output



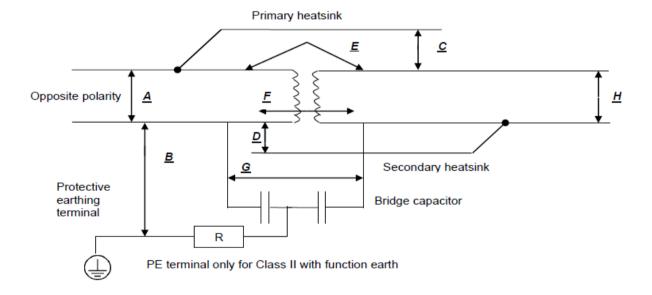
7.0 Illustrations

Illustration 2a - Spacings

(F1) Class II / Double insulated

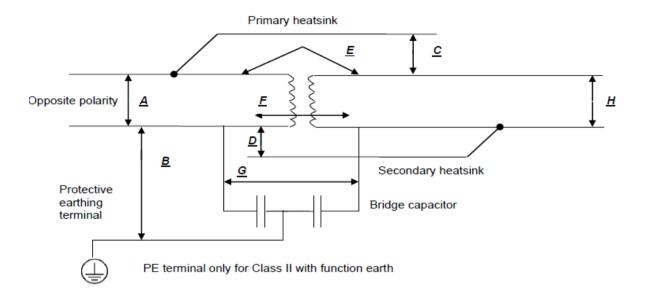


(F2) Isolated functional earth

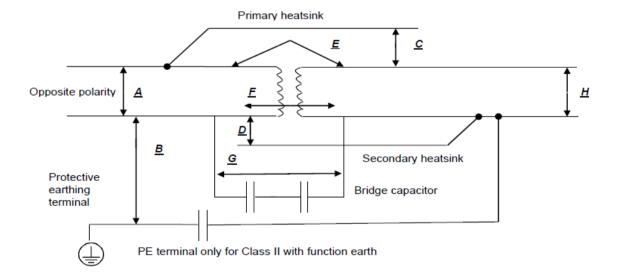


7.0 Illustrations

Illustration 2b - Spacings



(F3) Floating output/ Isolated common by capacitor



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7.0 Illustrations

Illustration 2c - Spacings

TABL	E: INSULATIO	N DIAG	RAM						Р
Pollut	Pollution degree					2			
	Overvoltage category:						II		_
Altitu	de			:	Up to 5000i m	m, use mul ultiple fact	tiple factor 1 or 1.48 for M	.29 for MOPI	P. –
	Additional details on parts considered as applied parts			red	⊠ None (See Claus	Are 🔲 Are e 4.6 for de	as tails)		_
Area	Number and type of Means of	СТІ		king age V _{sk}	Required creepage (mm)	Required clearanc e (mm)		Measured clearance (mm)	Remarks
	Protection: MOOP, MOPP		- 11113						
Α	1MOOP	IIIb	240		2.96	2.98	4.1	4.1	Mains opposite polarity
В	2MOPP	IIIb	240	-	8.0	6.45	8.2	8.2	Mains (plug pin) to enclosure (accessible position during normal use)
С	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
Н	2MOPP	IIIb	-	Max. 48	-	-		-	Accessible part per 8.4.2c)
Suppl	Supplementary Information:								

8.0 Test Summary

Evaluation Period 7-Jun-2021 to 7-Sep-2021 Project No. 210600861SHA

Sample Rec. Date 7-Jun-2021 Condition Prototype Sample ID. 0210604-45-003

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:

The following tests were performed:	
	AAMI ES60601-1:2005+A1
	CSA C22.2#60601-1:2014 Ed.3
Test Description	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
Cord anchorage	8.11.3.5
Cord guards	8.11.3.6
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

	IEC 60601-1-11:2015 Ed.2+A1		
	CSA C22.2#60601-1-11:2015 Ed.2		
Test Description	Clause		
Environmental condition test of transport and storage	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:	Kay Luo	Reviewed by:	Jack Cheng
Title:	Project engineer	Title:	Project reviewer
Signature:	tople	Signature:	Lakehong

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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 Medical Power Supply Product 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

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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.

If all standards on the ATM have the same standard title, the shared title or its abbreviation may be used in place of the examples above. Example: "Medical Electrical Equipment" or "MEE"; "Information Technology Equipment" or "ITE"; "Audio/Video Information And Communication Technology Equipment" or "A/V ICTE".

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.

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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 reevaluation.

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. Emiliana Zhou

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.

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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 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:				
<u>Product</u>	Test Voltage	Test Time		
All the product covered by this report	4000V	1s		
Between mains part and secondary circuits.				
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/ Project Handler/ Section Item Description of Change Proj # Site ID Reviewer None

Issued: 7-Sep-2021