1.0 Reference and Address					
Report Number	130801751SHA-001	Original Issued:	24-Oct-2013	Revised:	17-Apr-2017
Standard(s)	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (R2012) [AAMI ES60601-1:2005 +C1;A2] Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance [CSA C22.2#60601-1:2014 Ed.3] Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety & Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment & Medical Electrical Systems Used In The Home Healthcare Environment [AAMI HA60601-1-11:2015 Ed.2]				

Applicant	GlobTek, Inc.	Manufacturer	**GlobTek (Suzhou) Co., Ltd.**
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2.0 Product Description	
Product	Medical Power Supply
Brand name	GlobTek
Description	Products covered by this report are medical power supply module, which can be used as part of medical equipment. The different models are corresponding to two structure types respectively. One type is power adapter, which can be used with detachable power supply cord. Different appliance inlets can be interchangeable on the device, which can provide earthing connection or not. Protective earthing connection to secondary circuit by internal wiring is optional, so it can be Class I or Class II construction. Both two constructions were in consideration in this report. But only Class II adapter models are evaluated by 60601-1-11. Two pieces of outer enclosure are enclosed with ultrasonic welding and screws. The other type is open-frame power supply board, which is the same as adapter model except input and output terminals and traces on the board. 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 insulation construction of EUT is evaluated as 2MOPP in this report as customer's request.
Models	GT*41133-***-**, GT*961200P***** and GT*96900P*****
Model Similarity	GT*41133-***-**, GT*961200P***** and GT*96900P***** (The 1st "*" part can be 'M' or '-' or 'H' for market identification and not related to safety.) When model = GT*41133-***** The 2nd "*" denotes the rated output wattage designation, which can be "01" to "90", with interval of 1. The 3rd "*" denotes the standard rated output voltage designation, which can be "16", "24", "35" and "48". The 4th "*" part is optional, which can be "-0.1" to "-12.9" with interval of 0.1 to denote voltage deviation or blank to indicate no voltage different. The 3rd "*" and 4th "*" together denote the output voltage, with a range of 12 - 48 volts The 5th "*" =-T2 means desktop class II with C8 AC inlet =-T3A means desktop class I with C6 AC inlet =-F means Open Frame class I =-FW means Open Frame class II The last * denote any six character = 0-9 or A-Z or ()[] or – or blank for marketing purposes. When model = GT*961200P**** and GT*96900P**** The 2nd "*" denotes the rated output wattage designation, which can be "-01" to "-120", with interval of 1 and "-" can be omitted. 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 =-T3TAB means desktop class I with C14 AC inlet and housing with a tab. =-T3A means desktop class I with C6 AC inlet The last * denote any six character = 0-9 or A-Z or ()[] or – or blank for marketing purposes
Ratings	GT*961200P**** and GT*96900P****, Input:100-240V~,50-60Hz, 1.5A; GT*41133-*****,Input:100-240V~, 50-60Hz or 50-400Hz, 1.5A; Output: Refer to illustration No.1 for details.
Other Ratings	N/A
	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.

2.0 Product Description	
Conditions of Acceptability	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 16 (ME Systems) • 60601-1 Clause 17 (EMC), • Only Class II adapter models were evaluated by 60601-1-11. • 60601-1-11 Clause 7.1 (Usability of the accompanying documents), • 60601-1-11 Clause 7.4 (Instructions for use), • 60601-1-11 Clause 11 (Protection against strangulation or asphyxiation), • 60601-1-11 Clause 12 (Additional requirements for EMC) • 60601-1-11 Clause 13 (Additional requirements for Alarm system),

3.0 Product Photographs

Photo 1 - GT*41133 series External view of EUT without plug portion attached

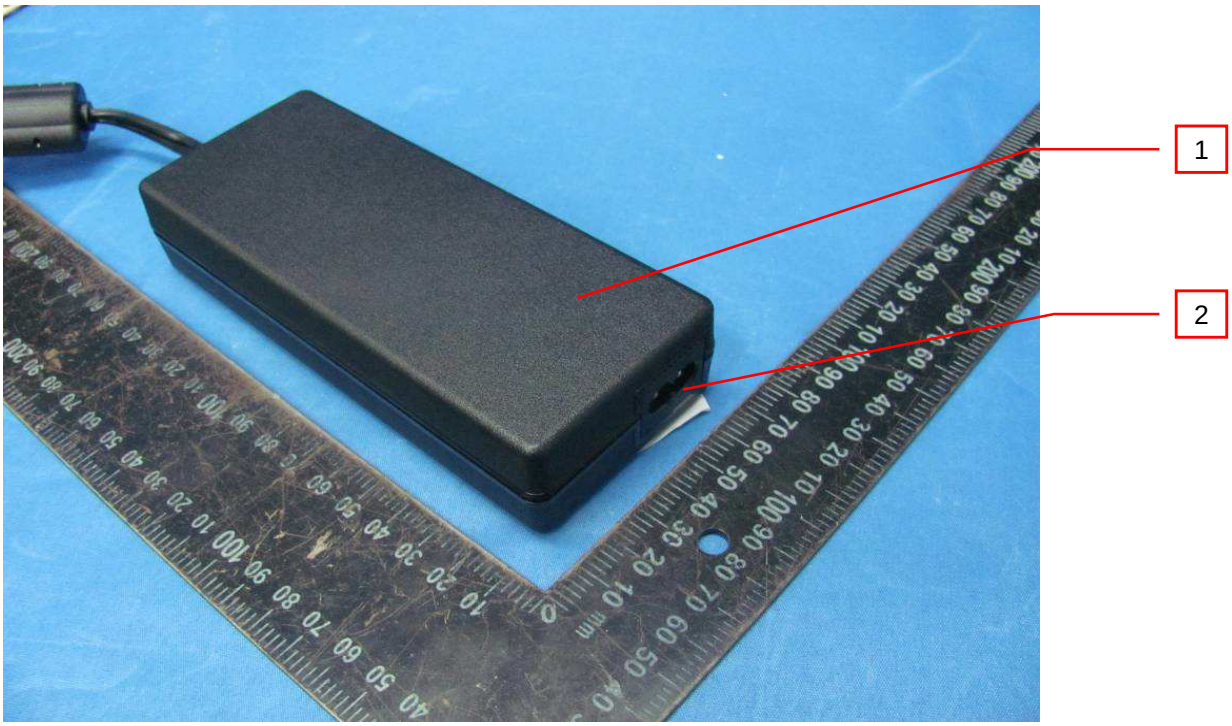
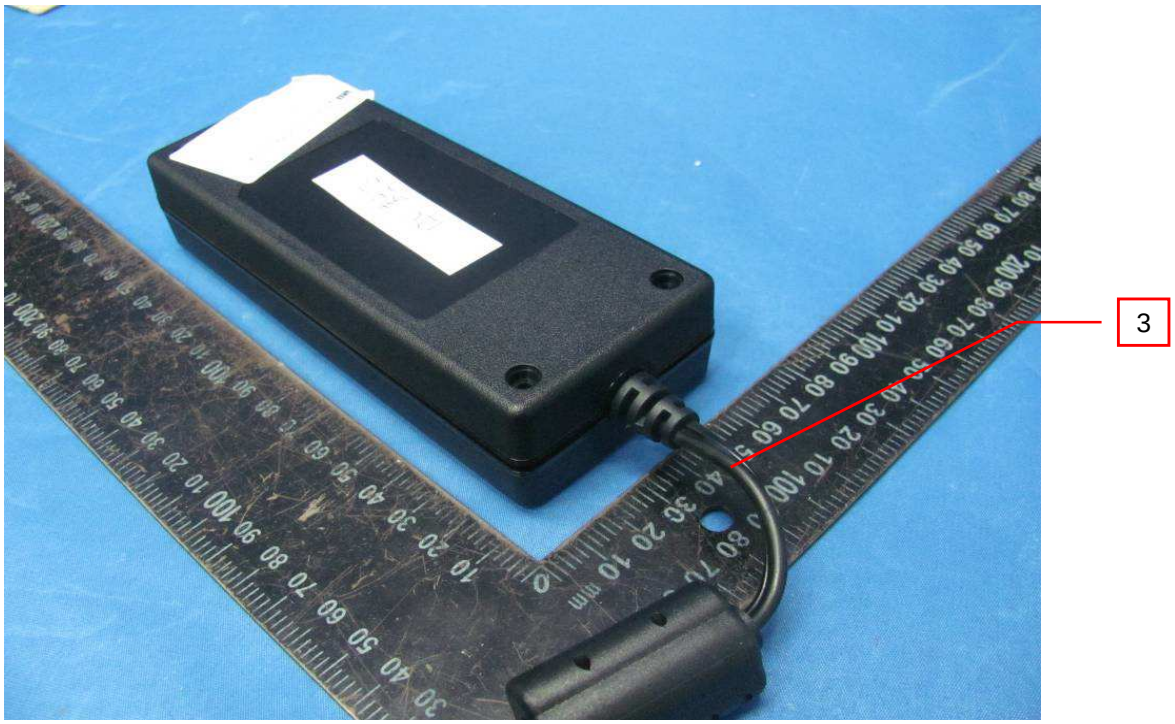


Photo 2 - GT*41133 series External view of EUT



3.0 Product Photographs

Photo 3 - GT*41133 series Component side view of PCB for power adapter model (Top heatsink

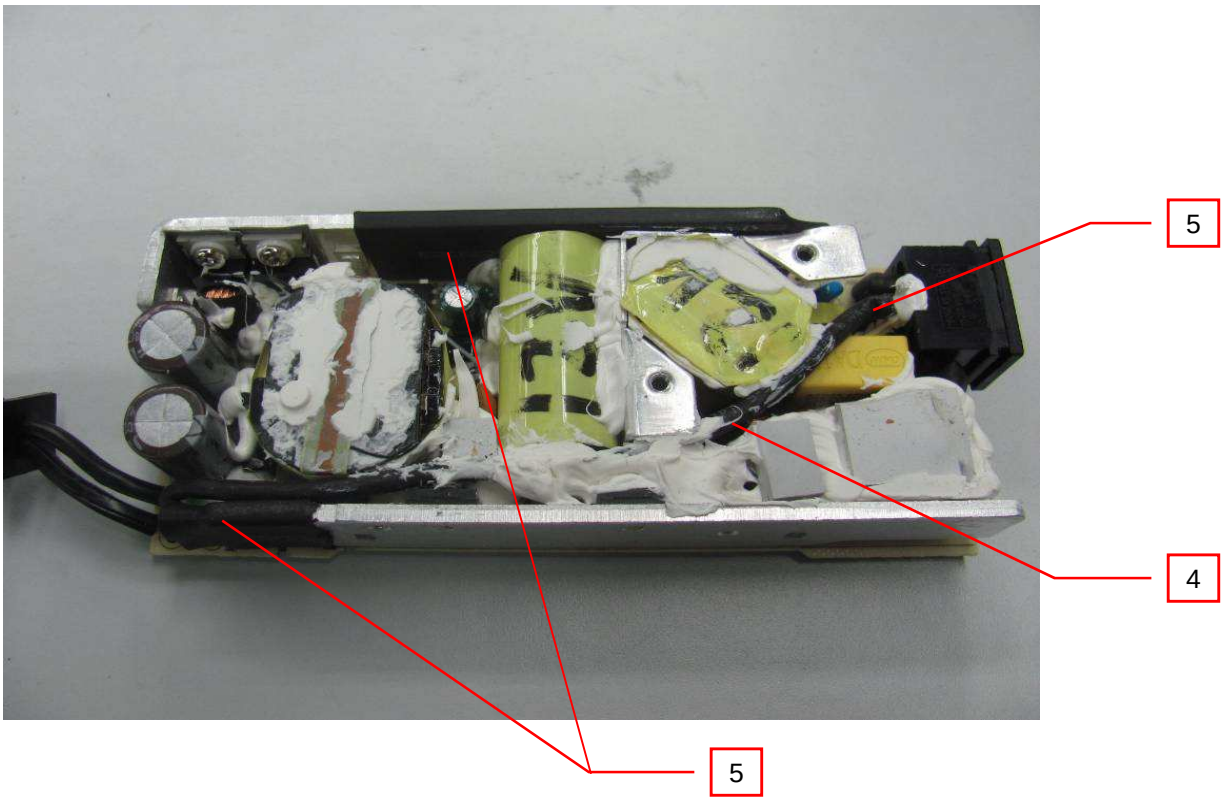
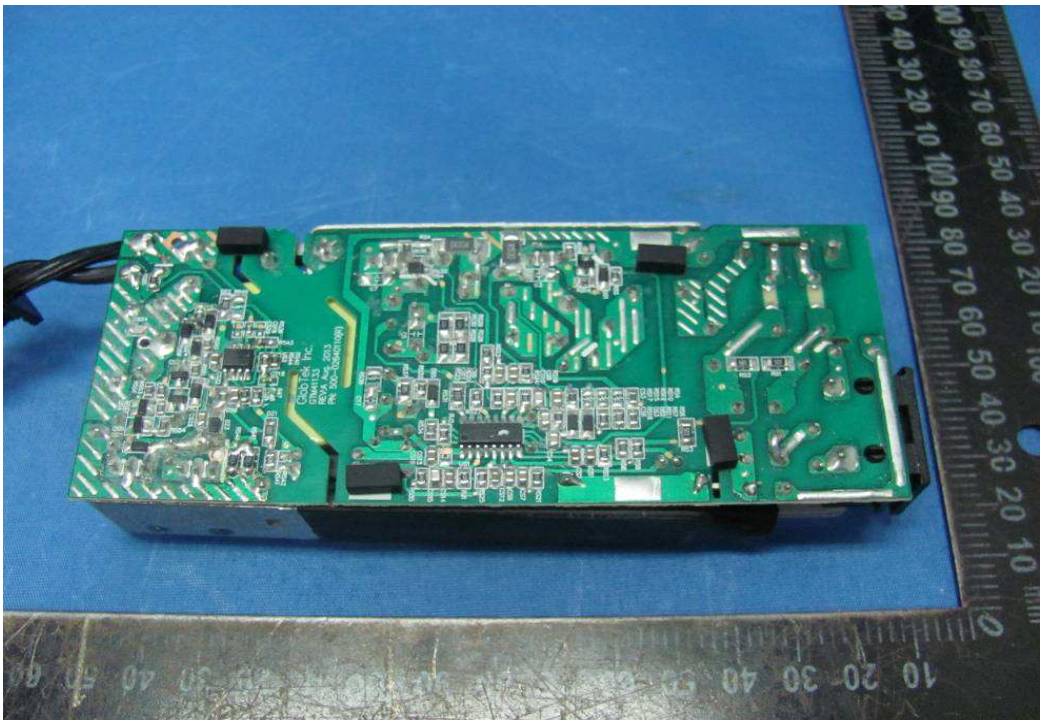


Photo 4 - GT*41133 series Soldering side view of PCB for power adapter model



3.0 Product Photographs

Photo 5 - GT*41133 series Component side view of PCB for open frame model

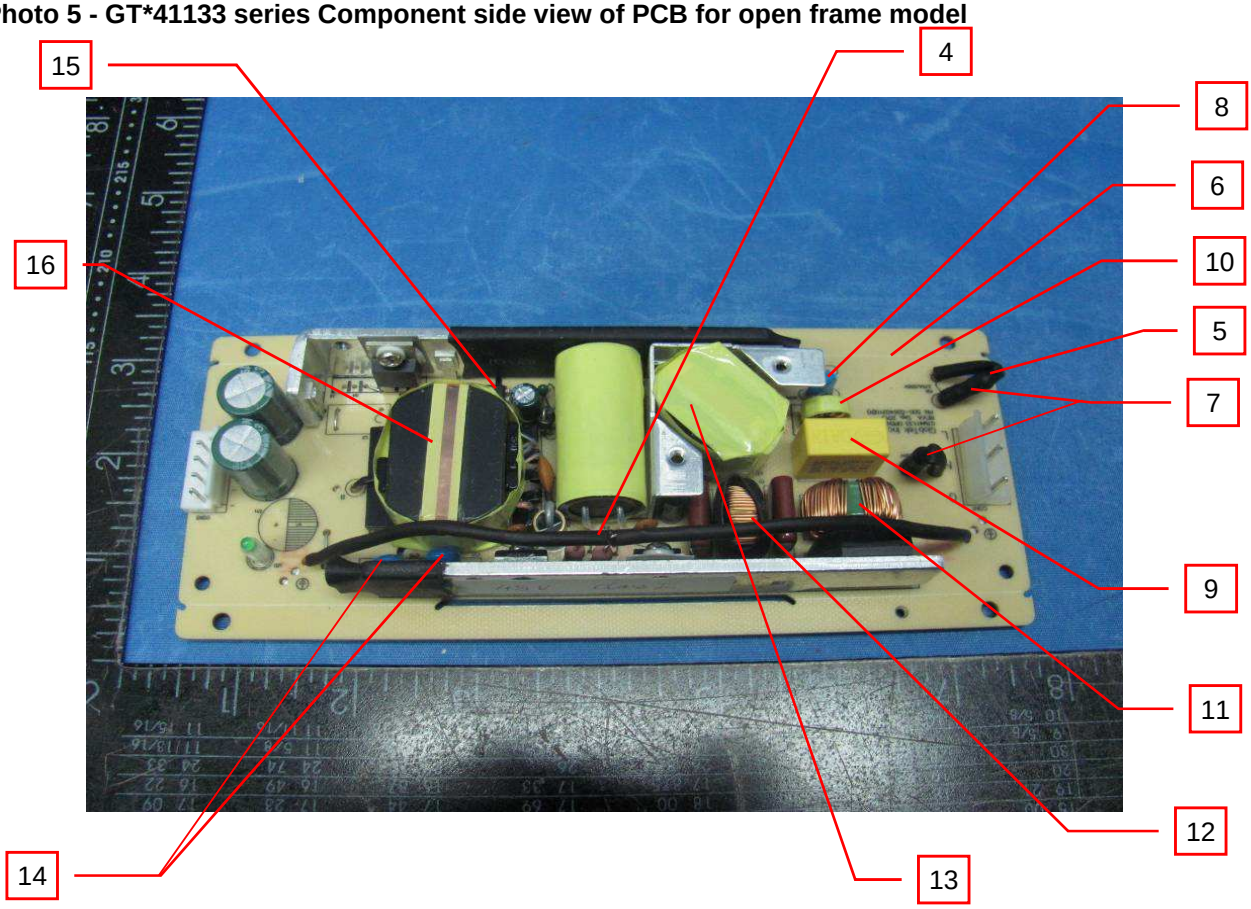
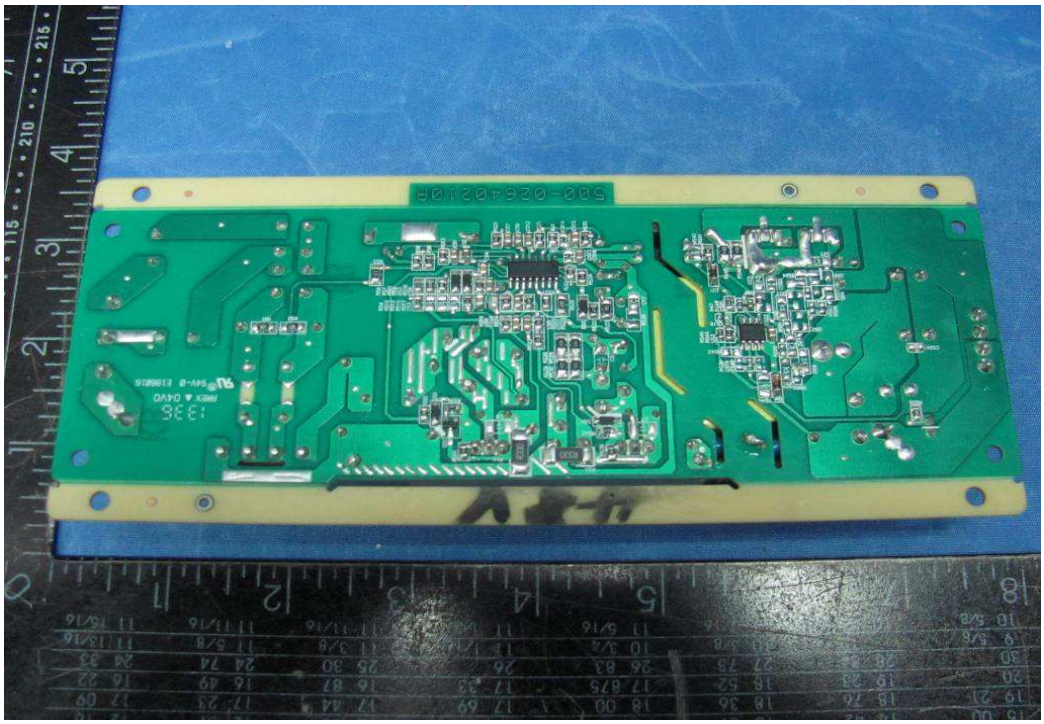


Photo 6 - GT*41133 series Soldering side view of PCB for open frame model



3.0 Product Photographs

Photo 7: GT*41133 series Internal view of EUT for power adapter model with top heatsink

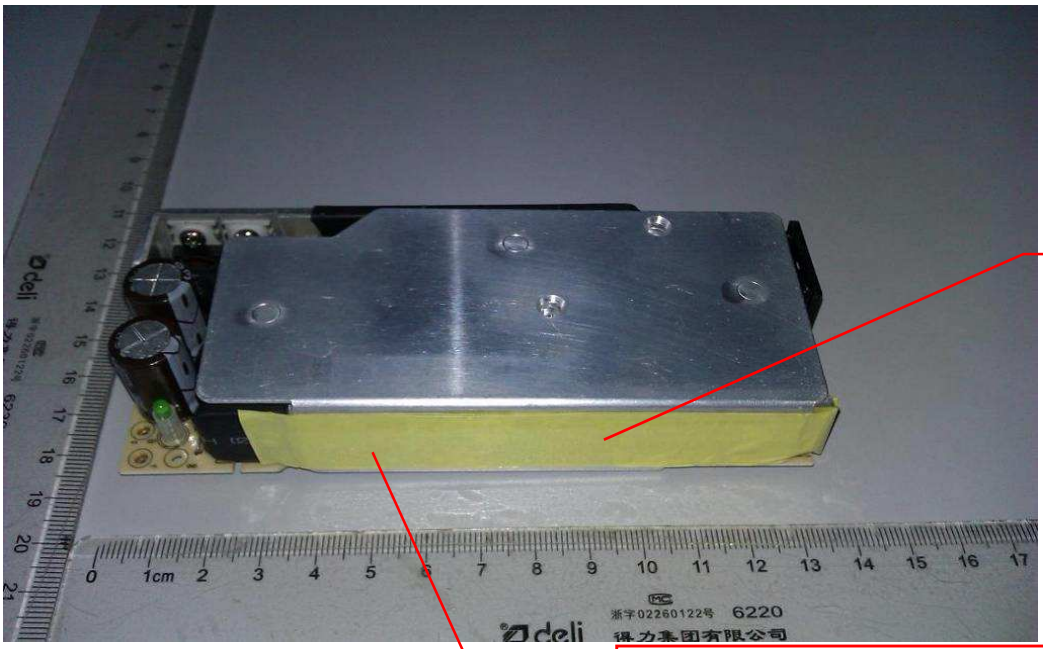
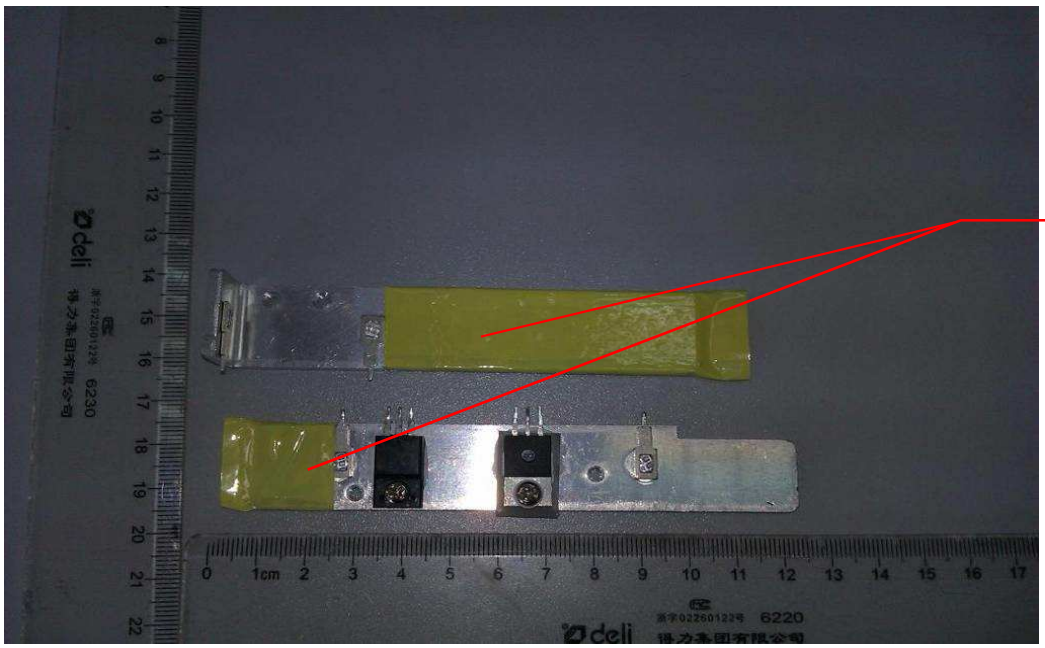


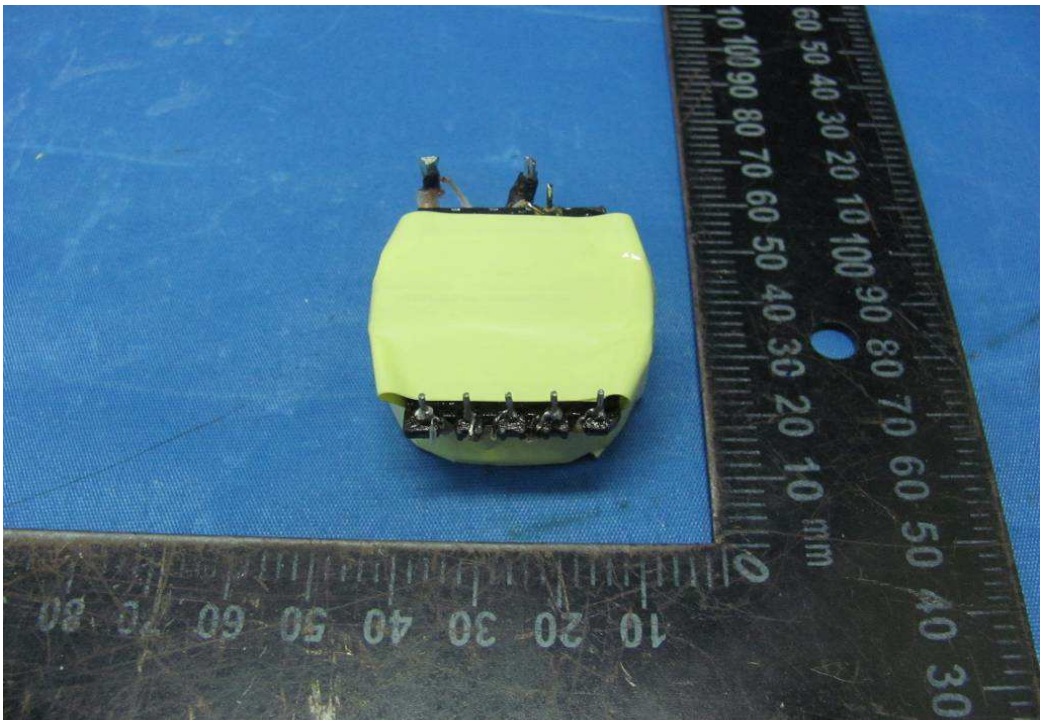
Photo 8 - GT*41133 series View of insulation protection on heatsink (2 layers of insulating tape or 2 layers of heat-shrinkable tube)



3.0 Product Photographs

Photo 9 - GT*41133 series External view of mains transformer

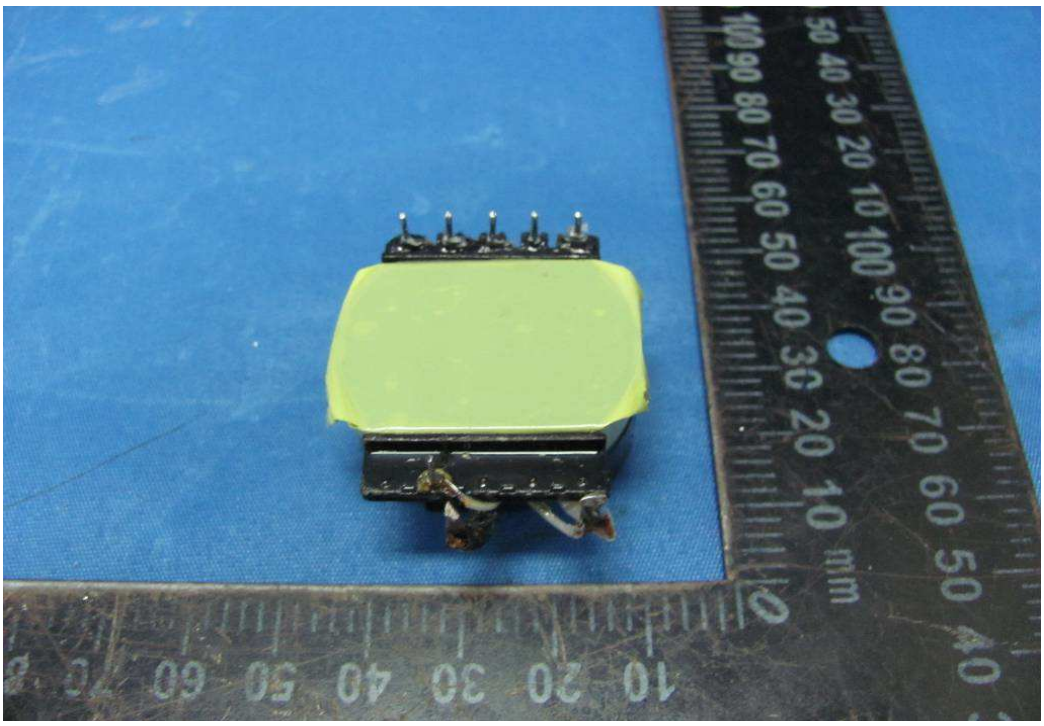
Photo 10 - GT*41133 series Pin-out view of mains transformer



3.0 Product Photographs

Photo 11 - GT*41133 series External view of mains transformer (shield copper foil)

Photo 12 - GT*41133 series Bottom view of mains transformer (The ferrite core is wrapped around 2 layers of insulating tape.)



3.0 Product Photographs

Photo 13 - GT*41133 series Primary winding view of mains transformer

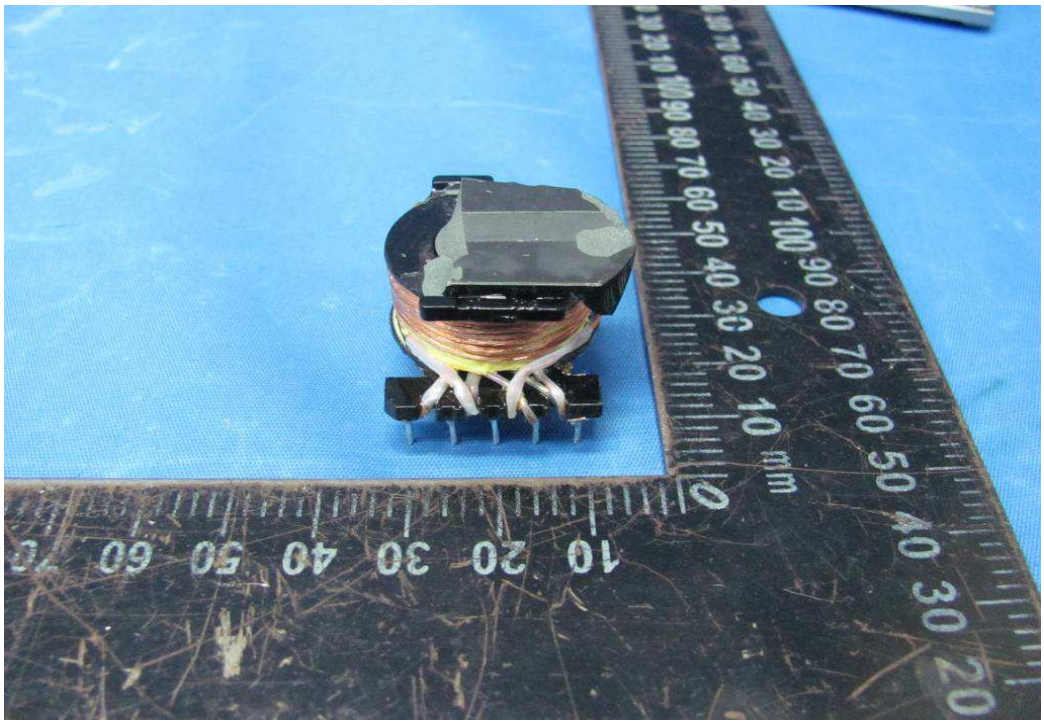
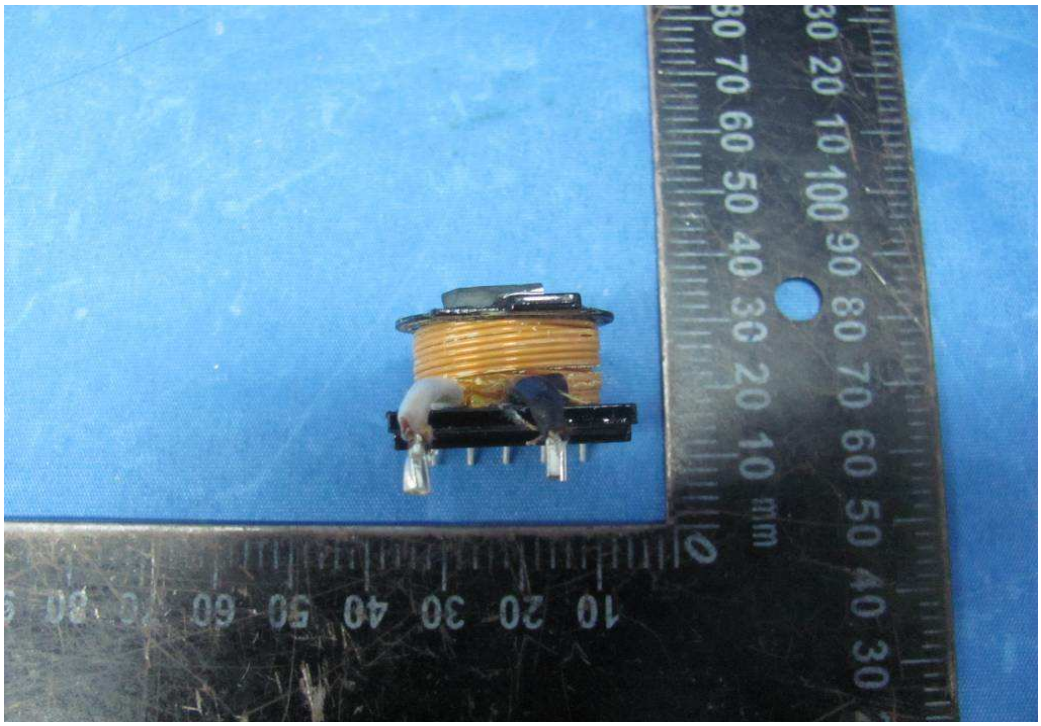


Photo 14 - GT*41133 series Secondary winding view of mains transformer (TIW)



3.0 Product Photographs

Photo 15: GT*96900P series, GT*961200P series external view of EUT

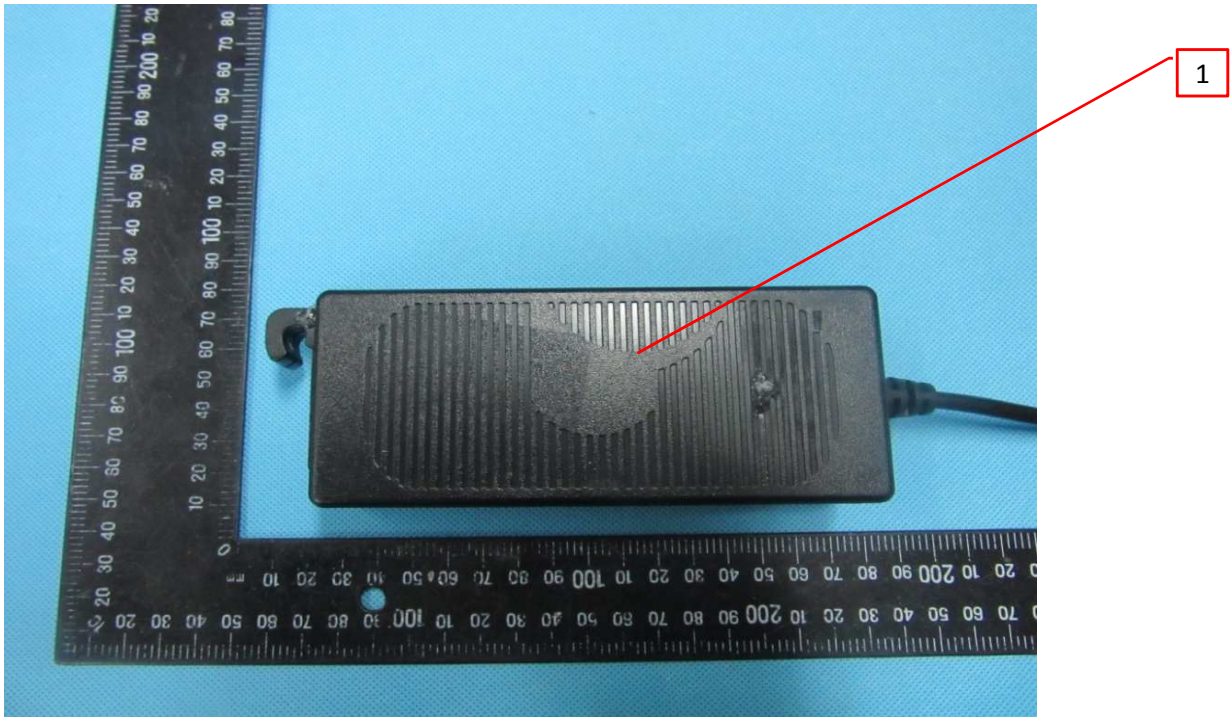


Photo 16: GT*96900P series, GT*961200P series external view of EUT

3.0 Product Photographs

Photo 17: GT*96900P series, GT*961200P series external view of EUT

Photo 18: GT*96900P series, GT*961200P series external view of EUT

3.0 Product Photographs

Photo 19 - GT*96900P series, GT*961200P series Internal view of EUT (Class II)

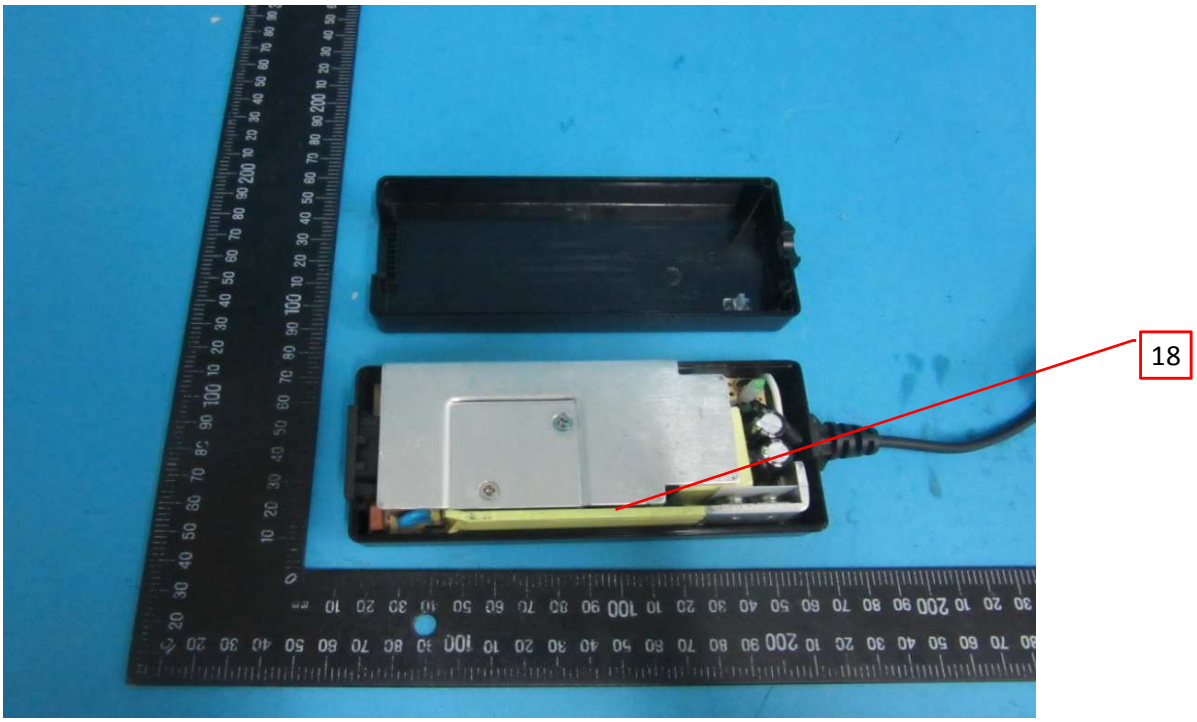
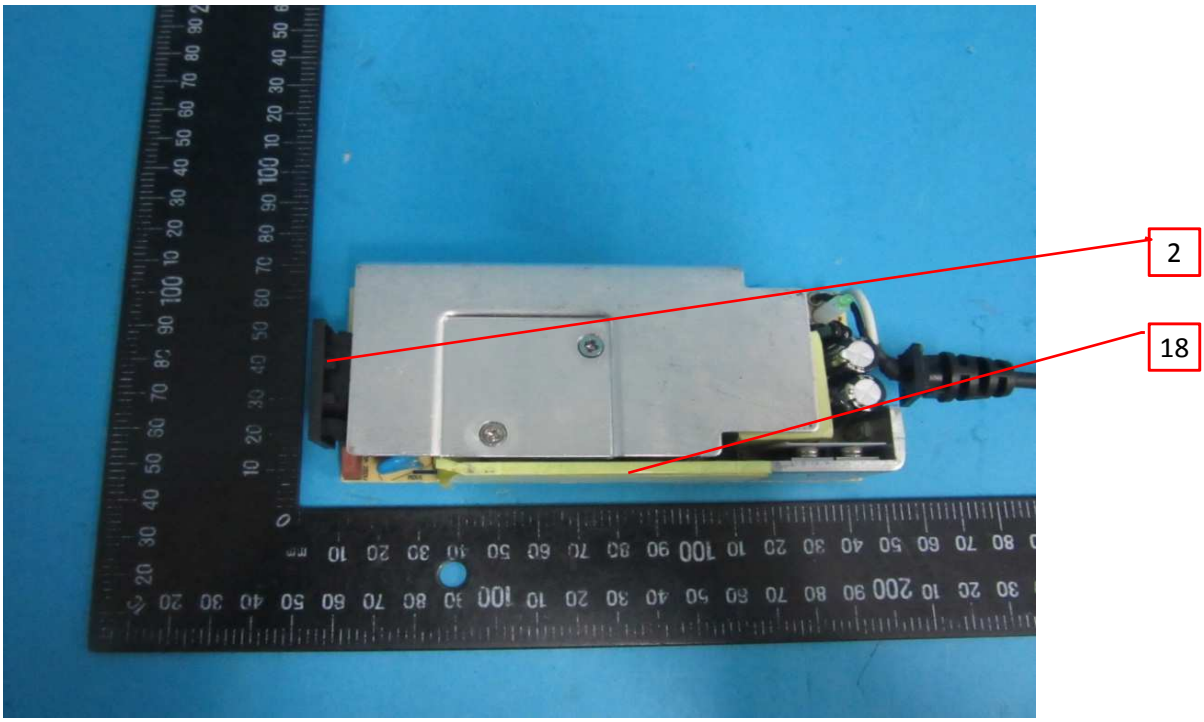


Photo 20 - GT*96900P series, GT*961200P series Internal view of EUT (Class II)



3.0 Product Photographs

Photo 21 - GT*96900P series, GT*961200P series Internal view of EUT (Class II)

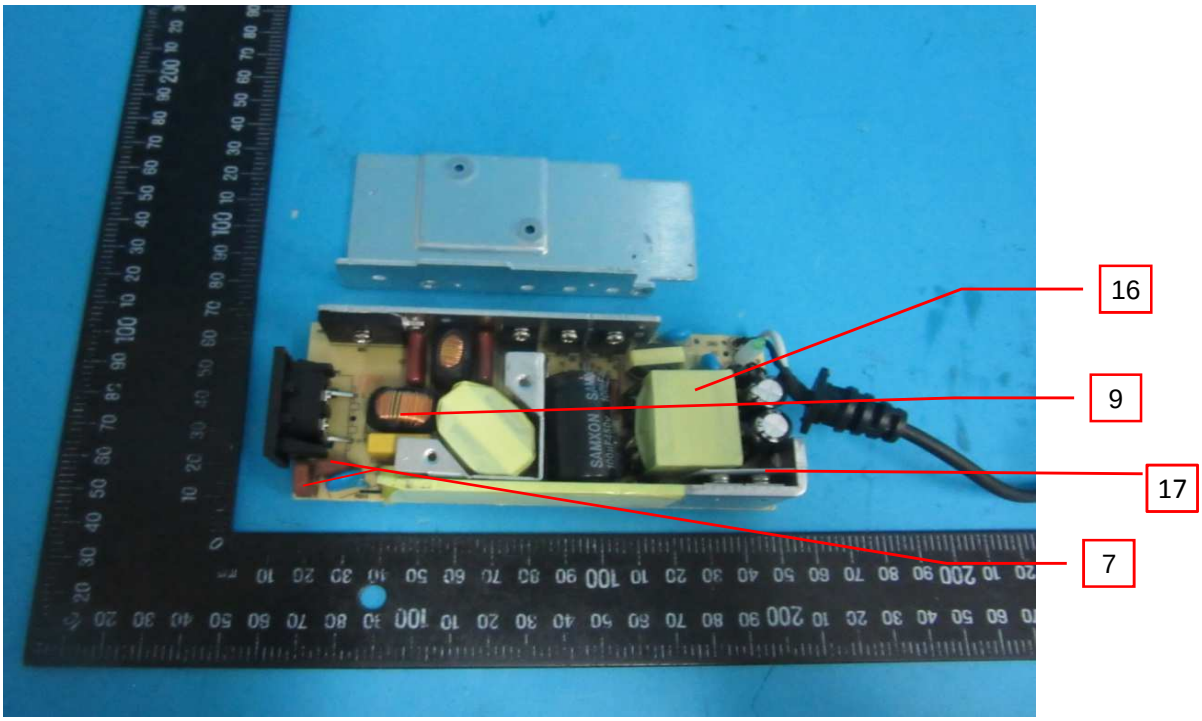
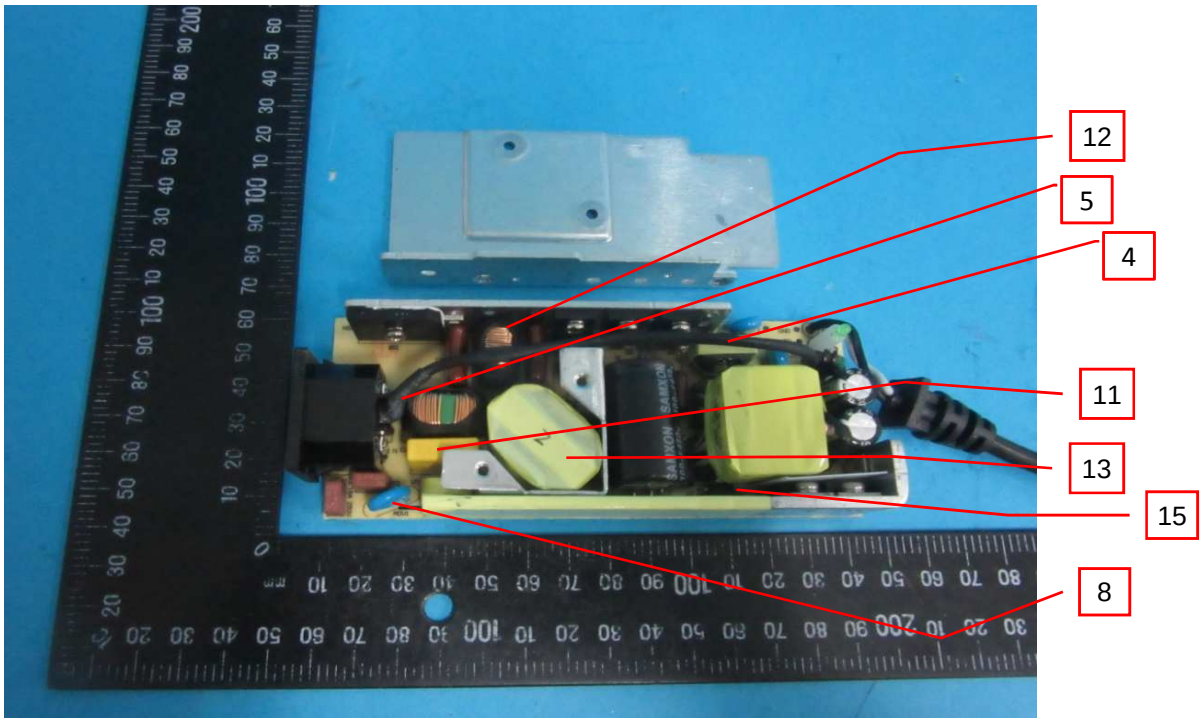


Photo 22 - GT*96900P series, GT*961200P series Internal view of EUT (Class I)



3.0 Product Photographs

Photo 23 - GT*96900P series, GT*961200P series Internal view of EUT (Class II)

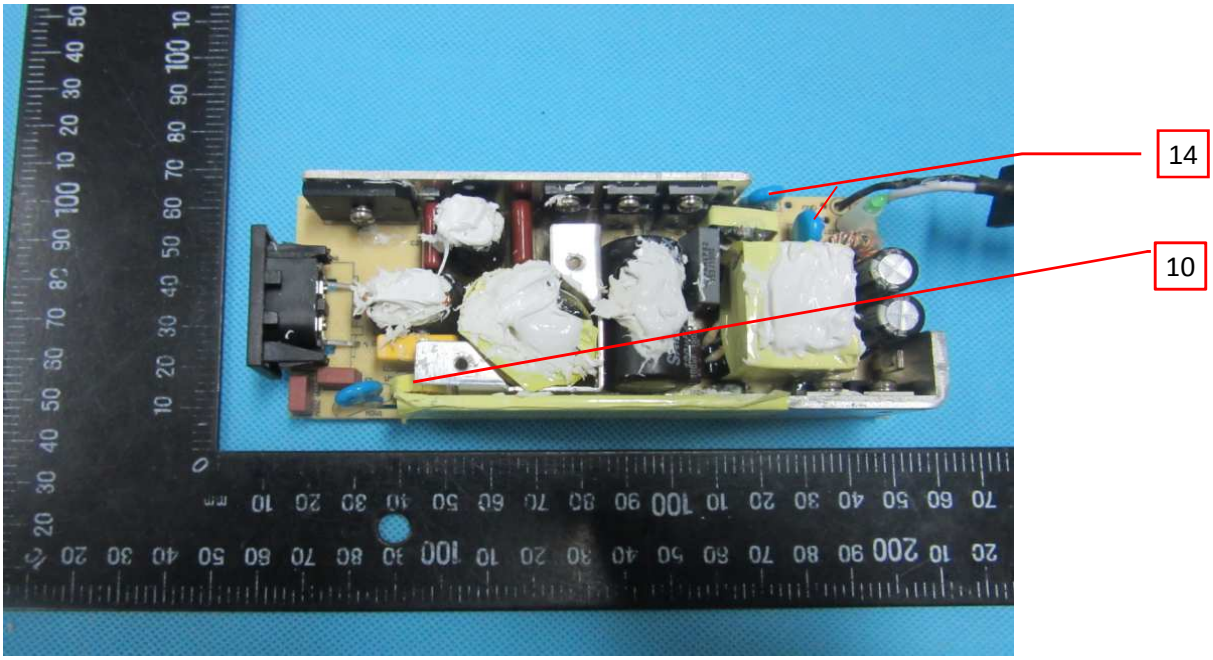
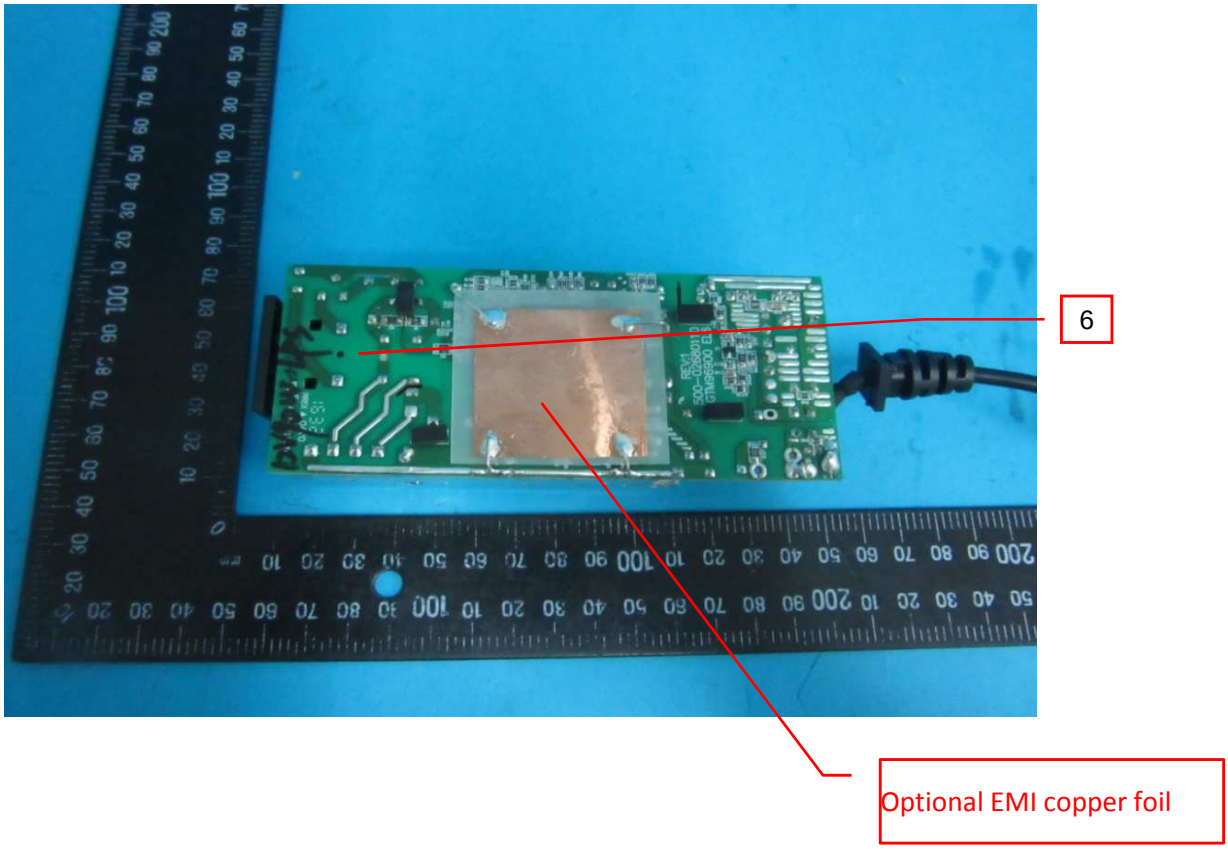


Photo 24 - GT*96900P series, GT*961200P series external view of PCB



3.0 Product Photographs

Photo 25 - GT*96900P series, GT*961200P series external view of PCB

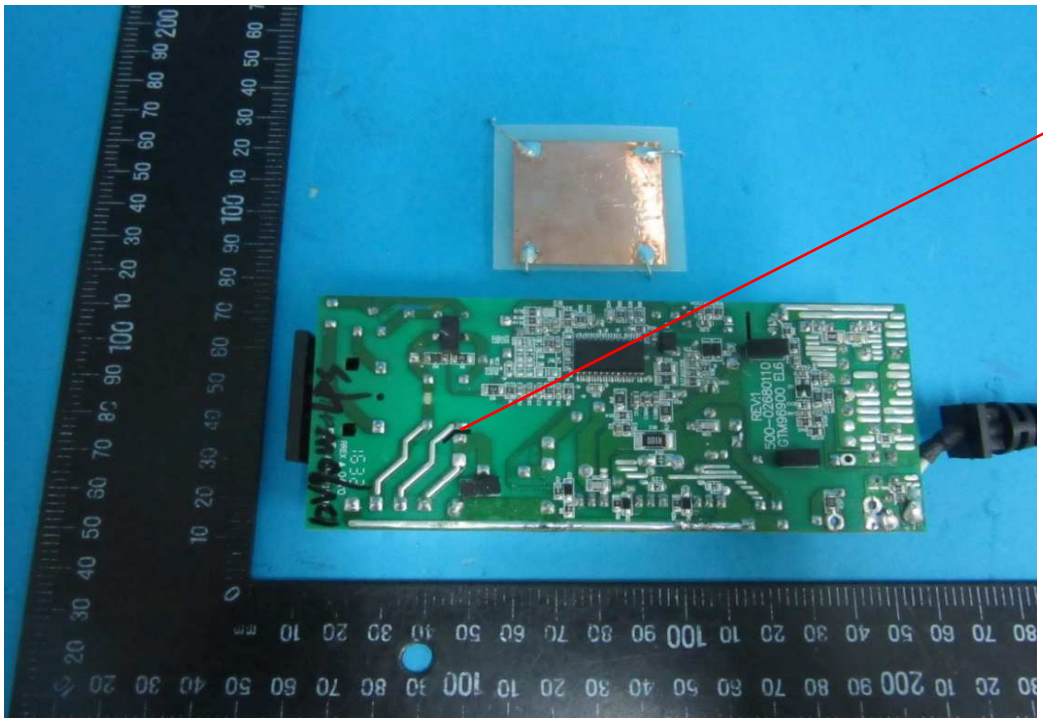
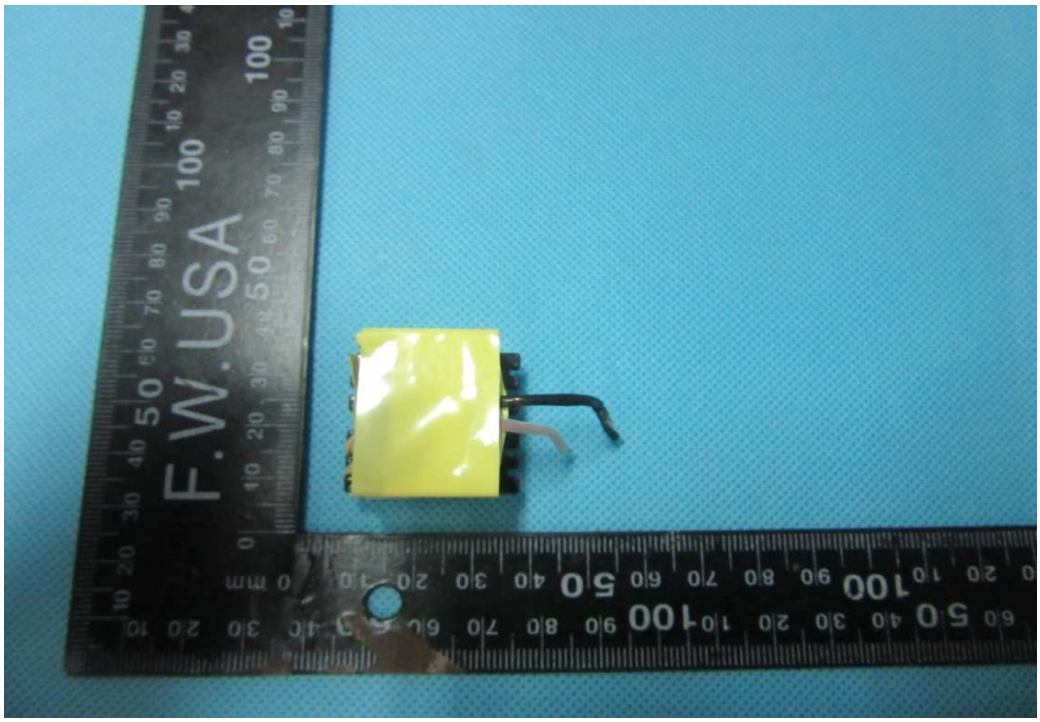


Photo 26 - GT*96900P series, GT*961200P series external view of mains transformer



3.0 Product Photographs

Photo 27 - GT*96900P series, GT*961200P series pin-out view of mains transformer

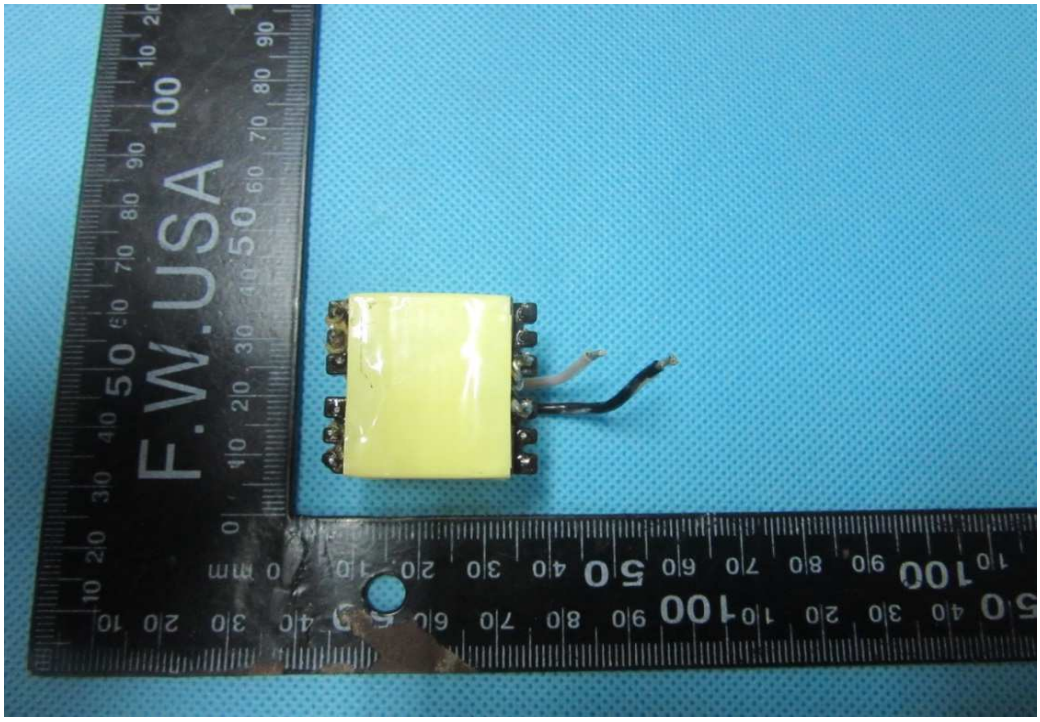
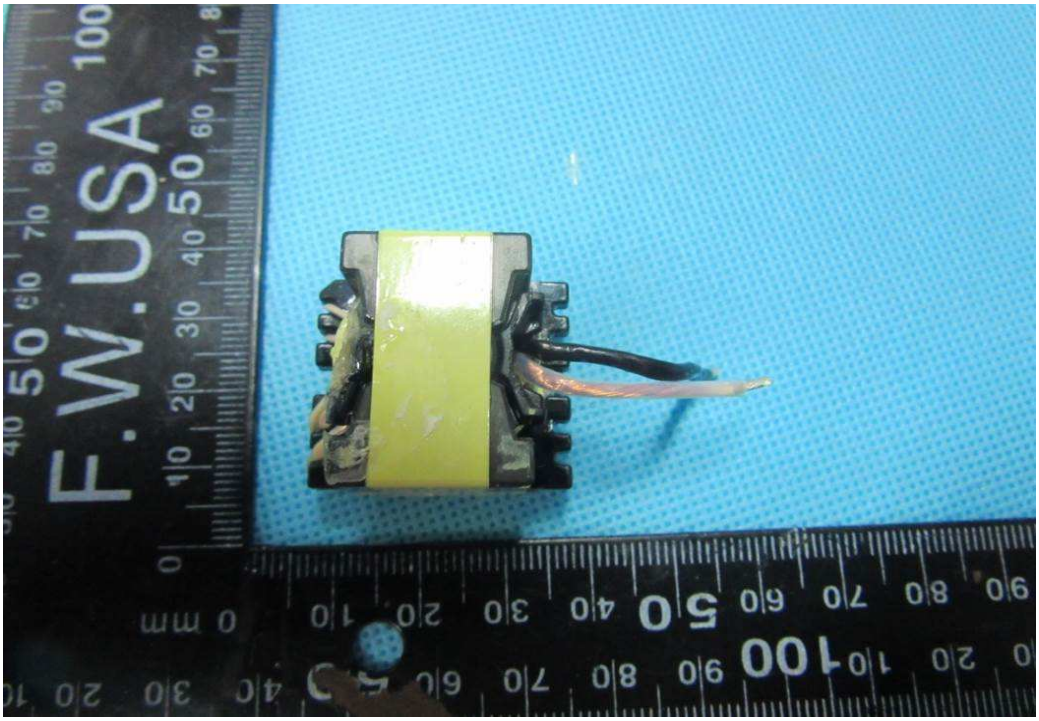


Photo 28 - GT*96900P series, GT*961200P series external view of mains transformer



3.0 Product Photographs

Photo 29 - GT*96900P series, GT*961200P series pin-out view of mains transformer

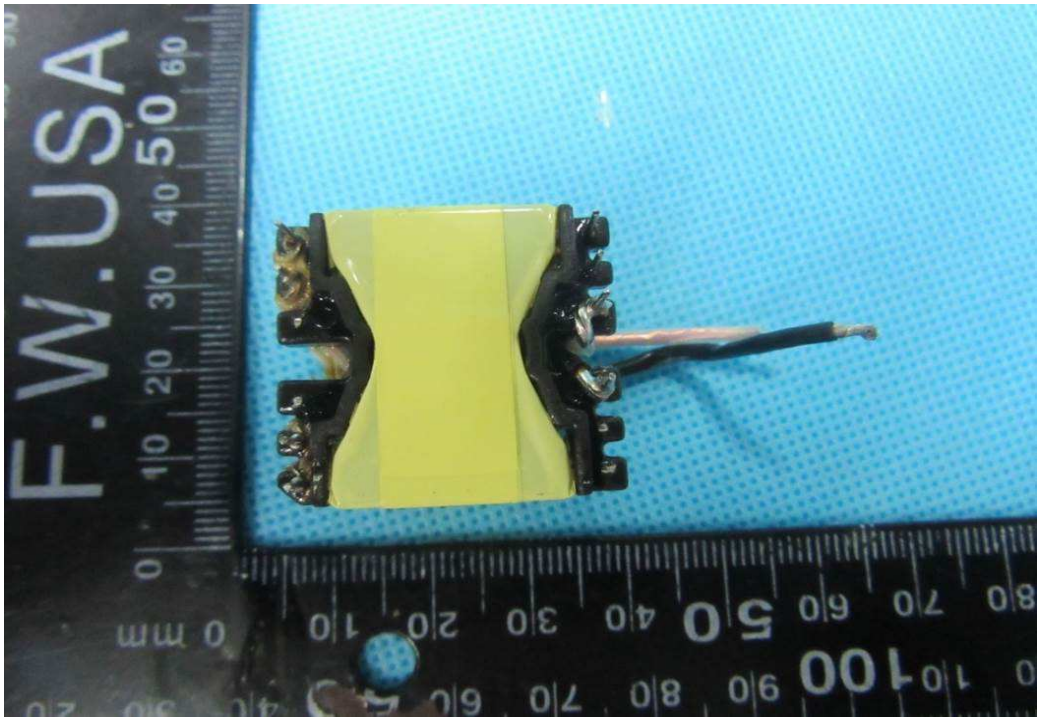
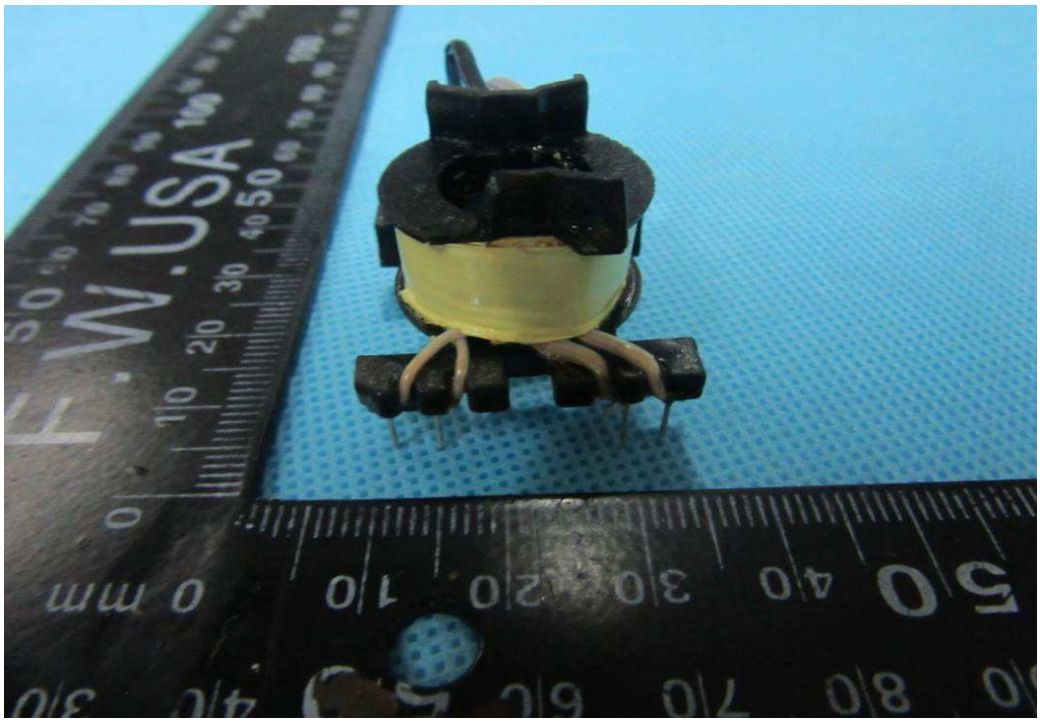


Photo 30 - GT*96900P series, GT*961200P series internal view of mains transformer

3.0 Product Photographs

Photo 31 - GT*96900P series, GT*961200P series internal view of mains transformer

Photo 32 - GT*96900P series, GT*961200P series primary winding view of mains transformer



3.0 Product Photographs

Photo 33 - GT*96900P series, GT*961200P series primary winding view of mains transformer (TIW)

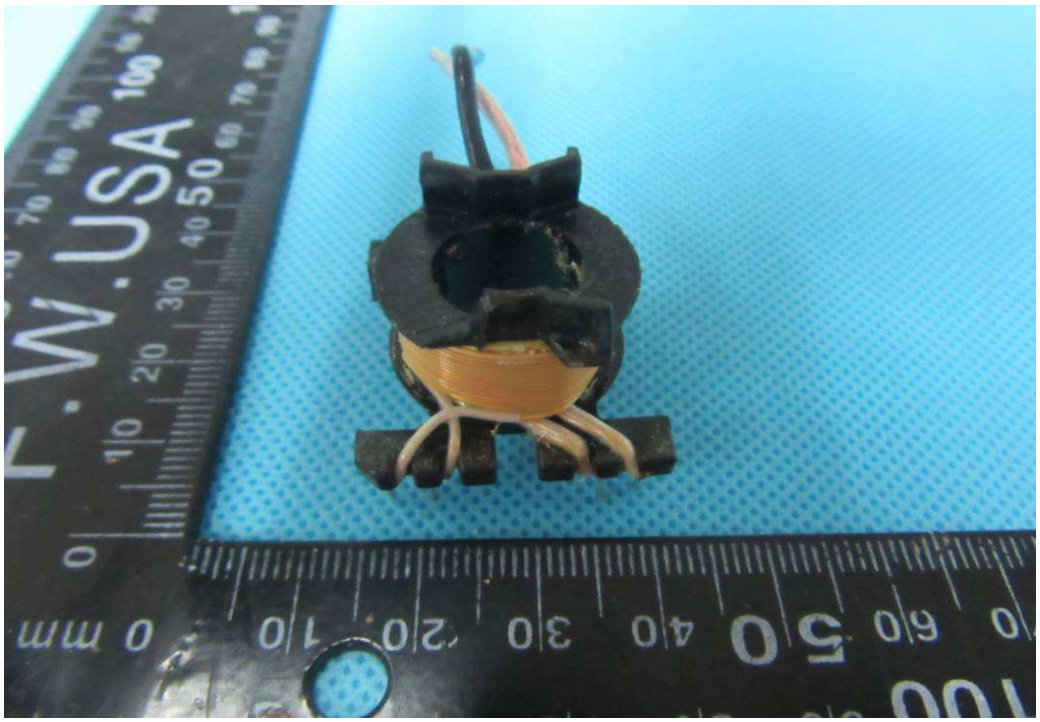
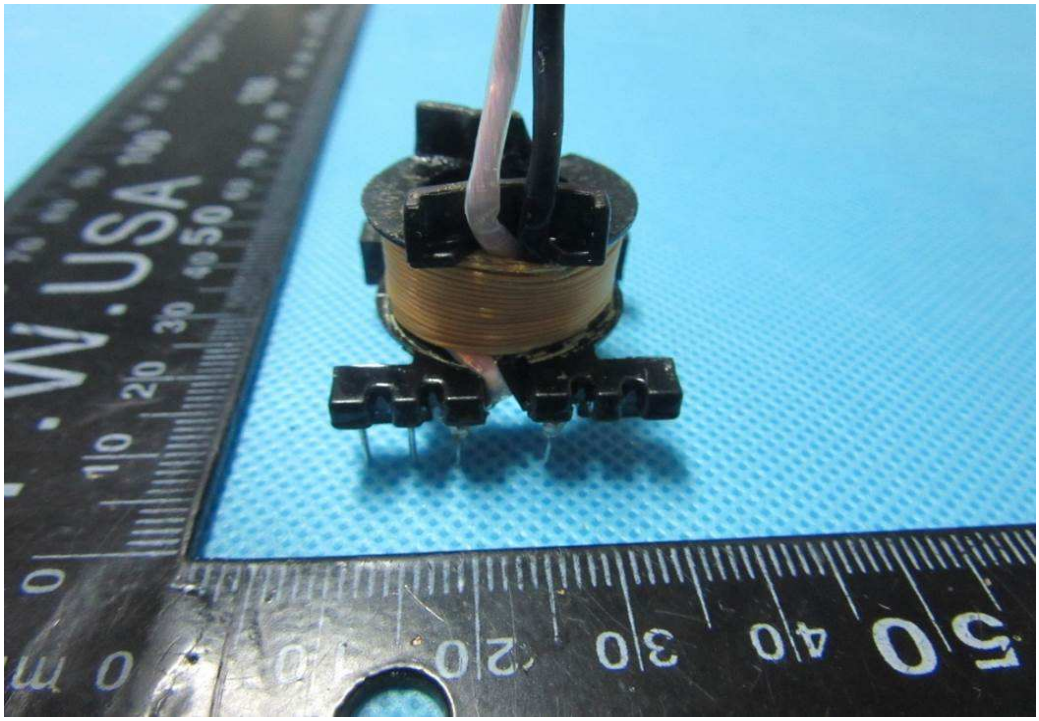


Photo 34 - GT*96900P series, GT*961200P series primary winding view of mains transformer



3.0 Product Photographs

Photo 35 - GT*96900P series, GT*961200P series primary winding view of mains transformer

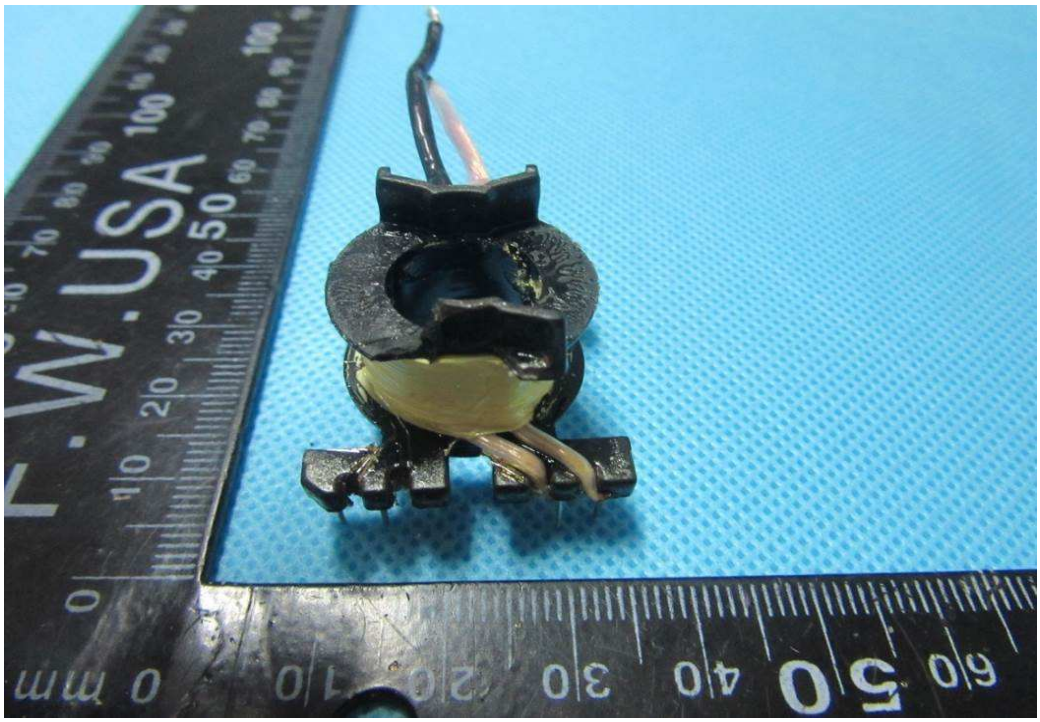
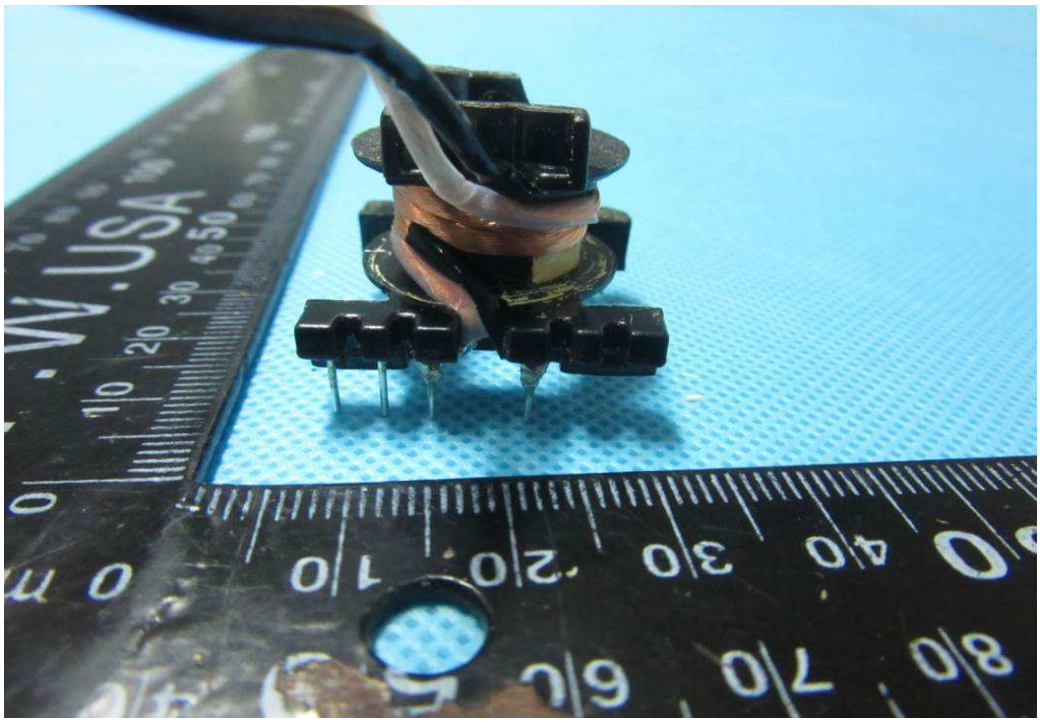


Photo 36 - GT*96900P series, GT*961200P series secondary winding view of mains transformer



3.0 Product Photographs

Photo 37 - GT*96900P series, GT*961200P series secondary winding view of mains transformer

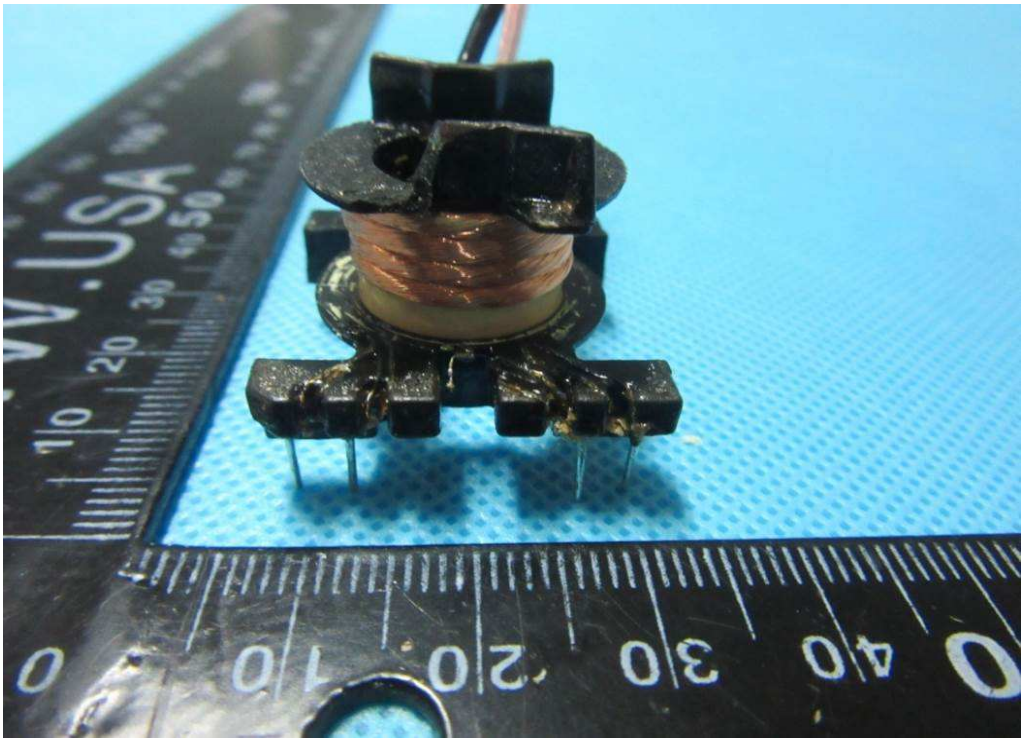


Photo 38 - GT*96900P series, GT*961200P series transformer bobbin

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, 15-18	1	Plastic enclosure	SABIC INNOVATIVE PLASTICS B V	SE1X SE1	PPE+PS, Min. V-1, Min. thickness: 2.0mm, 105°C	cURus
			SABIC INNOVATIVE PLASTICS B V	C2950	PC/ABS, Min. V-0, Min. thickness: 2.0mm, 85°C (For: GT*41133 series)	
			SABIC INNOVATIVE PLASTICS B V	CX7211 EXCY0098	PC/ABS, Min. V-1, Min. thickness: 2.0mm, 90°C (For: GT*96900 series, GT*41133 series)	
			SABIC INNOVATIVE PLASTICS B V	SE100	PPE+PS, Min. V-1, Min. thickness: 2.0mm, 95°C	
			SABIC INNOVATIVE PLASTICS B V	945	PC, V-0, Min. thickness: 2.0mm, 125°C	
			SABIC INNOVATIVE PLASTICS B V	HF500R	PC, V-0, Min. thickness: 2.0mm, 125°C	
			TEIJIN CHEMICALS LTD	LN-1250P LN-1250G	PC, Min. V-0, Min. thickness: 2.0mm, 115°C	
			CHI MEI Corporation	PA-765A	ABS, Min. V-0, Min. thickness: 2.0mm, 85°C (For: GT*41133 series)	
			CHI MEI Corporation	PC-540	PC/ABS, Min. V-0, Min. thickness: 2.0mm, 70°C (For: GT*41133 series)	
1, 20	2		Zhejiang LECI Electronics Co., Ltd.	DB-6	2.5A, 250Vac Standard sheet: C6	
			Rich Bay Co., Ltd.	R-30790 R-307		
			Sun Fair Electric Wire & Cable (HK)Co. Ltd.	S-02		
			TECX-UNIONS Technology Corporation	TU-333 series		
			Rong Feng Industrial Co., Ltd.	RF-190		
			Inalways Corporation	0724		
			Kunshan Dlk Electronics Technology Co., Ltd	CDJ-2		
			Zhejiang LECI Electronics Co., Ltd.	DB-8		
			Rich Bay Co., Ltd.	R-201SN90		
			Sun Fair Electric Wire & Cable (HK)Co. Ltd.	S-01		

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]
		AC inlet for Class I model or Class II model (alternative)	TECX-UNIONS Technology Corporation	SO-222	2.5A, 250Vac Standard sheet: C8	cURus
			Rong Feng Industrial Co., Ltd.	RF-180		
			Inalways Corporation	0721		
			Kunshan Dlk Electronics Technology Co., Ltd	CDJ-8		
			ZHE JIANG BEI ER JIA ELECTRONIC CO LTD	ST-A03-005		
			Zhejiang LECI Electronics Co., Ltd.	DB-14	10A, 250Vac Standard sheet: C14	
			Rich Bay Co., Ltd.	R-301SN		
			Sun Fair Electric Wire & Cable (HK)Co. Ltd.	S-03		
			TECX-UNIONS Technology Corporation	TU-301-S, TU-301-SP		
			Rong Feng Industrial Co., Ltd.	SS-120		
			Inalways Corporation	0711		
			Zhe Jiang Bei Er jia	ST-A01-003J		
			Rong Feng Industrial Co.,Ltd	SS-120	10A, 250Vac Standard sheet: C18 (For:GT*96900 series and GT*961200 series)	

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]
2, 17	3	Output cord only for adapter model	KUNSHAN NEW ZHICHENG ELECTRONICS TECHNOLOGIES CO LTD	1185 2464 2468 1015	Min. 20AWG, min. 300Vac, min. 80°C	cURus
			Various	Various	Min. 20AWG, min. 300Vac, min. 80°C	
3, 5, 22	4	Earthing wire for class I model only	KUNSHAN NEW ZHICHENG ELECTRONICS TECHNOLOGIES CO LTD	1015, 1007,1185	Min. 18AWG, min. 300Vac, min. 80°C	cURus
			ZHUANG SHAN CHUAN ELECTRICAL PRODUCTS (KUNSHAN) CO LTD			
			DONGGUAN CHUANTAI WIRE PRODUCTS CO LTD			
			YONG HAO ELECTRICAL INDUSTRY CO LTD			
			DONGGUAN GUNEETAL WIRE & CABLE CO LTD			
			SHENG YU ENTERPRISE CO LTD			
			KUNSHAN XINGHONGMEN G ELECTRONIC CO LTD			
			SUZHOU YEMAO ELECTRONIC CO LTD			
			Various			
3, 5, 22	5	Insulating tube used on Class I AC inlet pin, cartridge fuse and heatsink	SHENZHEN WOER HEAT-SHRINKABLE MATERIAL CO LTD	RSFR RSFR-H RSFR-HPF	600V, 125°C	cURus
			QIFURUI ELECTRONICS CO	QFR-h	600V, 125°C	
			DONGGUAN SALIPT CO LTD	SALIPT S-901-300 SALIPT S-901-600	Min. 300V, 125°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]
		(Optional)	GUANGZHOU KAIHENG ENTERPRISE GROUP	K-2 (+) K-2 (CB)	Min. 300V, 125°C	
			CHANGYUAN ELECTRONICS (SHENZHEN) CO LTD	CB-HFT	Min. 300V, 125°C	
5, 24	6	PCB material	WALEX ELECTRONIC (WUXI) CO LTD	T2	Min 1.6 mm thickness, min. V-0, 130°C	cURus
			DONGGUAN HE TONG ELECTRONICS CO LTD	CEM1		
			CHEERFUL ELECTRONIC	03 03A, 02		
			DONGGUAN DAYSUN ELECTRONIC CO LTD	DS2		
			SUZHOU CITY YILIHUA ELECTRONICS CO LTD	YLH-1		
			SHANGHAI AREX PRECISION ELECTRONIC CO LTD	02V0 04V0		
			BRITE PLUS ELECTRONICS (SUZHOU) CO LTD	DKV0-3A, DGV0-3A		
			SHENZHEN TONGCHUANGXIN ELECTRONICS CO LTD	TCX		
			Various	Various		

4.0 Critical Components						
Photo #	Item no.[1]	Name	Manufacturer/ trademark[2]	Type / model[2]	Technical data and securement means	Mark(s) of conformity [3]
5, 21	7	Fuse (FS1,FS2 or F1, F2) (FS2 or F2 is optional) (FS1, FS2 for GT*41133 series, F1, F2 for GT*96900 series, GT*961200 series)	Conquer Electronics Co., Ltd.	MST	T3.15A, 250Vac, interrupting rating 35A	cURus
			Ever Island Electric Co., Ltd. and Walter Electric	2010	T3.15A, 250Vac, interrupting rating 130A	
			Bel Fuse Ltd.	RST	T3.15A, 250Vac, interrupting rating 100A	
			Cooper Bussmann LLC	SS-5	T3.15A, 250Vac, interrupting rating 35A	
			Zhongshan Lanbao Electrical Appliances Co., Ltd.	RTI-10	T3.15A, 250Vac, interrupting rating 50A	
			Dongguan Better Electronics Technology Co., Ltd.	932	T3.15A, 250Vac, interrupting rating 100A	
			Hollyland Company Limited	5ET	T3.15A, 250Vac, interrupting rating 63A	
			Sunny East Enterprise Co. Ltd.	CFD	T3.15A, 250Vac, interrupting rating 50A	
			Conquer Electronics Co., Ltd.	MET	T3.15A, 250Vac, interrupting rating 35A	
			Shenzhen Lanson Electronics Co. Ltd.	SMT	T3.15A, 250Vac, interrupting rating 35A	
5, 22	8	Varistor (MOV1) (optional)	JOYIN CO LTD	10N471K 14N471K	Maximum continuous voltage: 300Vac	cURus
			CENTRA SCIENCE CORP	10D471K 14D471K		
			THINKING ELECTRONIC INDUSTRIAL CO LTD	TVR10471K TVR14471K		
			SUCCESS ELECTRONICS CO LTD	SVR10D471K SVR14D471K		
			Walsin Technology Co., Ltd.	14D471K		
			CERAMATE TECHNICAL CO LTD	GNR10D471K GND14D471K		
			BRIGHTKING (SHENZHEN) CO LTD	10D471K 14D471K		
			LIEN SHUN ELECTRONICS CO LTD	14D471K		

4.0 Critical Components

Photo #	Item no.[1]	Name	Manufacturer/ trademark[2]	Type / model[2]	Technical data and securement means	Mark(s) of conformity [3]
5, 21	9	X capacitor (CX1) (Optional)	Cheng Tung Industrial Co., Ltd.	CTX	(For GT*96900 series, GT*961200 series: Max. 0.22µF) (For GT*41133 series: Max. 0.47µF) 310Vac, 110°C, type X2 or X1	cURus
			Tenta Electric Industrial Co. Ltd.	MEX	(For GT*96900 series, GT*961200 series: Max. 0.22µF) (For GT*41133 series: Max. 0.47µF) 275Vac, 100°C, type X1	
			Ultra Tech Xiphi Enterprise Co. Ltd.	HQX	(For GT*96900 series, GT*961200 series: Max. 0.22µF) (For GT*41133 series: Max. 0.47µF), 275Vac, 110°C, type X2	
			Okaya Electric Industries	RE series	(For GT*96900 series, GT*961200 series: Max. 0.22µF) (For GT*41133 series: Max. 0.47µF), 275Vac, 100°C, type X2	
			Joey Electronics (Dong Guan) Co., Ltd.	MPX	(For GT*96900 series, GT*961200 series: Max. 0.22µF) (For GT*41133 series: Max. 0.47µF), 310Vac, 110°C, type X2	
			Yuon Yu Electronics Co. Ltd.	MPX	(For GT*96900 series, GT*961200 series: Max. 0.22µF) (For GT*41133 series: Max. 0.47µF), 275Vac or 300Vac, 110°C, type X2	
			VISHAY Capacitors Belgium NV	F1772	(For GT*96900 series, GT*961200 series: Max. 0.22µF) (For GT*41133 series: Max. 0.47µF) 440Vac, 100°C, type X2	
			Winday Electronic Industries Co., Ltd.	MPX	(For GT*96900 series, GT*961200 series: Max. 0.22µF) (For GT*41133 series: Max. 0.47µF), 275Vac, 100°C, type X2	
			Dain Electronics Co., Ltd.	MPX, MEX and NPX	(For GT*96900 series, GT*961200 series: Max. 0.22µF) (For GT*41133 series: Max. 0.47µF), 275Vac, 110°C, type X2	

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]
			Sinhua Electronics (Huzhou) Co., Ltd.	MPX	(For GT*96900 series, GT*961200 series: Max. 0.22µF) (For GT*41133 series: Max. 0.47µF) 300Vac, 110°C, type X1	
			Jiangsu Xinghua Huayu Electronics Co., Ltd.	MPX	(For GT*96900 series, GT*961200 series: Max. 0.22µF) (For GT*41133 series: Max. 0.47µF) 275Vac, 100°C, type X2	
			Shenzhen Jinghao Capacitor Co., Ltd.	CBB62B	(For GT*96900 series, GT*961200 series: Max. 0.22µF) (For GT*41133 series: Max. 0.47µF) 250Vac or 280Vac or 305Vac, 110°C, type X2	
			Foshan Shunde Beijiao Hua Da Electric Industrial Co., Ltd.	HD-MKP	(For GT*96900 series, GT*961200 series: Max. 0.22µF) (For GT*41133 series: Max. 0.47µF) 275Vac, 105°C,type X2	
			Foshan Shunde Chuang Ge	MKP-X2	(For GT*96900 series, GT*961200 series: Max. 0.22µF) (For GT*41133 series: Max. 0.47µF), 275Vac, 105°C, type X2	
			Hongzhi Enterprises Ltd.	MPX	(For GT*96900 series, GT*961200 series: Max. 0.22µF) (For GT*41133 series: Max. 0.47µF), 275Vac, 100°C, type X2	
5, 23	10	Line filter (LF1) (Optional)	GlobTek/ZhongTong/HEJIA/BOAM/	LF001	Class A	NR
5, 22	11	Line filter LF2 (Optional)	GlobTek/ZhongTong/HEJIA/BOAM/	LF002 (For model:GT*41133 series) LF026 (model:GT*96900P series, GT*961200P series)	Class A	NR

4.0 Critical Components						
Photo #	Item no.[1]	Name	Manufacturer/ trademark[2]	Type / model[2]	Technical data and securement means	Mark(s) of conformity [3]
5, 22	12	Line filter (LF3 For model:GT*41133 series) (L1 For model:GT*96900 series, GT*961200 series) (Optional)	GlobTek/ZhongTong/HEJIA/BOAM/	LF003	Class A	NR
5, 22	13	PFC Chock (L2) (Optional)	GlobTek/ZhongTong/HEJIA/BOAM/	LF004(For model:GT*41133 series) , LF028 (model:GT*96900P series, GT*961200P series)	Class A	NR
5, 23	14	Y-Capacitor (CY1, CY2) (optional)	SUCCESS ELECTRONICS CO LTD	SE SB	Type Y1, min. 250V, min. 125°C, (For GT*96900 series, GT*961200 series: max. 2200pF,) (For GT*41133 series, max. 1000pF)	cURus
			TDK CORPORATION	CD		
			MURATA MFG CO LTD	KX		
			WALSIN TECHNOLOGY CORP	AH		
			JYA-NAY CO LTD	JN		
			HAOHUA ELECTRONIC CO	CT7		
			Jyh Chung Electronic Co., Ltd.	JD		
			WELSON INDUSTRIAL CO LTD	WD		
			JERRO ELECTRONICS CORP	JX-series		
5, 22	15	Optocoupler (U2)	LITE-ON Technology Corporation	LTV-817	isolation voltage 5300Vrms	cURus
			Everlight Electronics Co., Ltd.	EL817	isolation voltage 5000Vrms	

4.0 Critical Components						
Photo #	Item no.[1]	Name	Manufacturer/ trademark[2]	Type / model[2]	Technical data and securement means	Mark(s) of conformity [3]
5, 9-14, 21, 26-38	16	Transformer (T1)	GlobTek/ZhongTong/BOAM	TF012 TF013 TF014 TF015 (For:GT*41133 series)	Class B, with insulation system and critical component listed below. Refer to illustration No. 7&8 for Spec.	NR
				TF047 TF075 TF048 TF076 TF072 TF077 TF049 TF078 TF073 TF079 TF050 TF074 (For:GT*96900 series and GT*961200 series)	Class B, with insulation system and critical component listed below. Refer to illustration No. 13 for Spec.	NR
5, 9-14, 21, 26-38	16a	Insulation system	GLOBTEK INC	GTX-130-TM	Class 130(B)	cURus
			WUXI ZHONGTONG ELECTRONICS CO LTD	ZT-130		
			SHAN DONG BOAM ELECTRIC CO LTD	BOAM-01		
5, 9-14, 21, 26-38	16b	Magnet wire (Primary)	PACIFIC ELECTRIC WIRE & CABLE (SHENZHEN) CO LTD	UEWN/U	130°C	cURus
			PACIFIC ELECTRIC WIRE & CABLE (SHENZHEN) CO LTD	UEWS/U		
			JUNG SHING WIRE CO LTD	UEW-4 UEY-2		
			JIANGSU HONGLIU MAGNET WIRE TECHNOLOGY CO LTD	2UEW/130		
			CHANGZHOU DAYANG WIRE & CABLE CO LTD	2UEW/130		
			WUXI JUFENG COMPOUND LINE CO LTD	2UEWB		

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]
			JIANGSU DARTONG M & E CO LTD	UEW		
			SHANDONG SAINT ELECTRIC CO LTD	UEW/130		
			ZHEJIANG LANGLI ELECTRIC EQUIPMENTS CO LTD	UEW		
5, 9-14, 21, 26-38	16c	Insulating tape	3M COMPANY ELECTRICAL MARKETS DIV (EMD)	1350F-1 1350T-1 44	Min.130°C	cURus
			BONDTEC PACIFIC CO LTD	370S		
			JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CO LTD	PZ CT WF		
			JINGJIANG JINGYI ADHESIVE PRODUCT CO LTD	JY25-A		
			CHANG SHU LIANG YI TAPE INDUSTRY CO LTD	LY-XX		
5, 9-14, 21, 26-38	16d	Bobbin	CHANG CHUN PLASTICS CO LTD	T375J T375HF	V-0, 150°C, thickness 0.45 mm min.	cURus
			SUMITOMO BAKELITE CO LTD	PM-9820		
			HITACHI CHEMICAL CO LTD	CP-J-8800		
5, 9-14, 21, 26-	16e	Triple-insulated wire (Secondary winding)	GREAT LEOFLON INDUSTRIAL CO LTD	TRW(B)	Reinforced insulation, Class B(130°C)	cURus
			COSMOLINK CO LTD	TIW-M		
			FURUKAWA ELECTRIC CO LTD	TEX-E		
			SHENZHEN JIUDING NEW MATERIAL CO LTD	DTIW-B		

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]
38			CHANGYUAN ELECTRONICS (SHENZHEN) CO LTD	CB-TIW		
			E&B TECHNOLOGY CO LTD	E&B-XXXB E&B-XXXB-1		
			TOTOKU ELECTRIC CO LTD	TIW-2		
5, 9-14, 21, 26-38	16f	PTFE tubing	Great Holding Industrial Co Ltd	TFT / TFS	Min. 300V, 200°C	cURus
			Changyuan Electronics (Shenzhen) Co Ltd	CB-TT-T, CB-TT-S	Min. 300V, 200°C	
			Shenzhen Woer Heat-Shrinkable Material Co Ltd	WF	600V, 200°C	
21	17	Mylar Insulating sheet beside the heatsink (optional)	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, 105°C	
			FORMEX,DIV OF IL TOOL WORKS INC, FRMRLY FASTEX, DIV OF IL TOOL WORKS INC	FORMEX GK series	V-0, min. 0.4 mm thickness, 115°C	
			SABIC INNOVATIVE PLASTICS US L L C	FR60 series FR63 series FR65 series FR7 series FR700 series	V-0, min. 0.4 mm thickness, 130°C	
			MIANYANG LONGHUA FILM CO LTD	PP-BK-20 PP-BK-17 PP-BK-18	VTM-0, min. 0.4 mm thickness, 80°C	
			CHENGDU KANGLONGXIN PLASTICS CO LTD	KLX FRPC-1860B	VTM-0, Min. 0.4mm thickness, 80°C	
			CHENGDU KANGLONGXIN PLASTICS CO LTD	KLX PP WT-10 series	VTM-0, min. 0.4 mm thickness, 110°C	
7, 8, 19, 20	18	Insulating tape wrapping around the heatsink (Optional)	3M COMPANY ELECTRICAL MARKETS DIV (EMD)	1350F-1 1350T-1	Min.130°C	cURus
			BONDTEC PACIFIC CO LTD	370S		
			JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CO LTD	PZ CT		

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]
			JINGJIANG JINGYI ADHESIVE	JY25-A		
			CHANG SHU LIANG YI TAPE INDUSTRY CO	LY-XX		

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
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) 2-3 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.
8. Schematics - Refer to Illustration No(s). 4-5 & 10-11 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. 6 & 12 for details.
10. Cautionary Markings - Refer to illustrations No. 6 & 12 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.

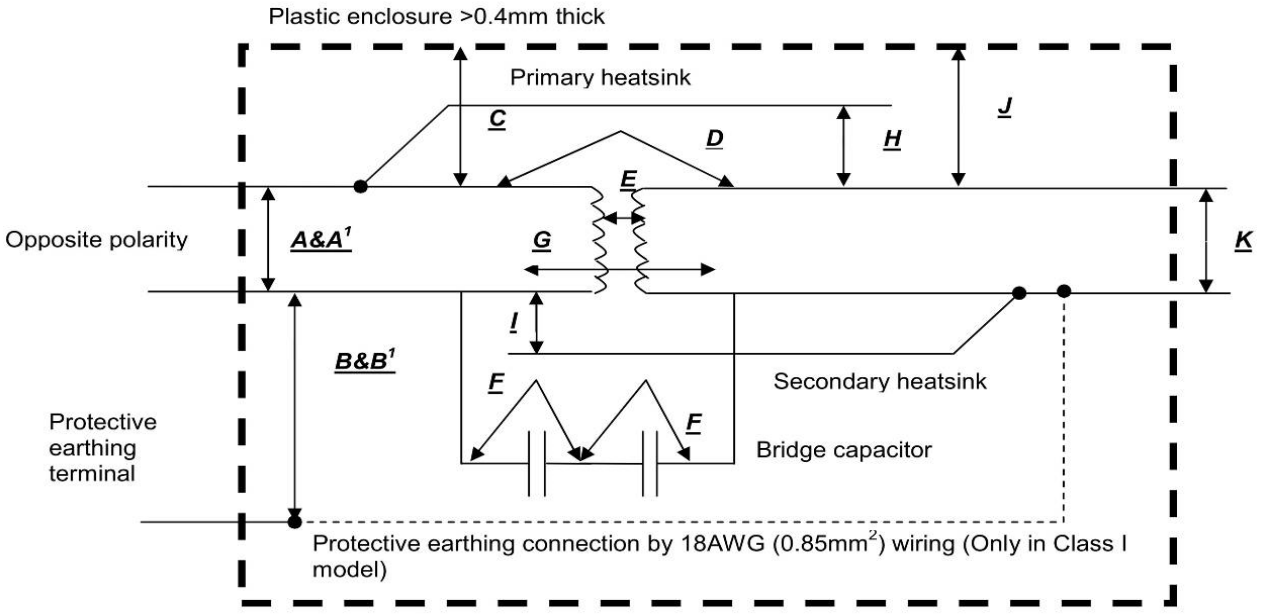
7.0 Illustrations

Illustration 1 - Model list

Model	Rated output voltage range	Max. rated output current	Max. rated output power	Transformer designation
GT*41133-*16*-**	12-16Vdc	7.5A	90W	TF013
GT*41133-*24*-**	16.1-24Vdc	5.6A	90W	TF014
GT*41133-*35*-**	24.1-35Vdc	3.73A	90W	TF015
GT*41133-*48*-**	35.1-48Vdc	2.56A	90W	TF012

Model	Output Voltage	Max. output current	Max. output power
GT*96900P**-T2/T2A/T3/T3A/T3TAB*	12-54Vdc	7.5A	90W
GT*961200P**-T2/T2A/T3/T3A/T3TAB*	12-54Vdc	9.2A	120W

Illustration 2 - INSULATION DIAGRAM



7.0 Illustrations

Illustration 3 - GT*41133 series TABLE: Insulation diagram (measured values)

TABLE: INSULATION DIAGRAM		P
Pollution degree ..... :	2	—
Overvoltage category ..... :	II	—
Altitude ..... :	Up to 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	–	3.0[9]	3.0[2]	4.1	4.1	Opposite polarity of mains part
A[1]	MOOP	IIIb	240	–	3.0[9]	3.0[2]	4.2	4.2	Opposite polarity of mains part
B	MOPP	IIIb	240	340	4.0	3.3[2]	5.0	5.0	Mains parts to PE terminal (On power inlet)
B[1]	MOPP	IIIb	240	340	4.0	3.3[2]	4.2	4.2	Mains parts to PE terminal (Along PCB trace)
C	2MOPP	IIIb	240[4]	–	7.9[6]	6.5[2]	8.0[3]	8.0[3]	Internal mains part to accessible outer enclosure (Only for power adapter model)
D	2MOPP	IIIb	240[4]	–	7.9[6]	6.5[2]	8.2[8]	8.2[8]	Mains parts to secondary pin-out (Optocoupler)
E	2MOPP	IIIb	357[4]	–	10.9[6]	9.1[2]	11.0[7]	11.0[7]	Secondary side (including ferrite) to primary pin-outt (Transformer)
F	MOPP (Each) x 2	IIIb	240[4]	–	4.0[6]	3.3[2]	6.0	6.0	Primary side to secondary side (Y capacitor x 2)
G	2MOPP	IIIb	240V	–	7.9[6]	6.5[2]	12.4	12.4	Mains parts to secondary parts (Nearest points along PCB trace)
H	2MOPP	IIIb	240[4]	–	7.9[6]	6.5[2]	10.0[8]	10.0[8]	Primary heatsink to secondary circuit
I	2MOPP	IIIb	240[4]	–	7.9[6]	6.5[2]	10.0[8]	10.0[8]	Primary circuit to secondary heatsink
J	2MOPP	IIIb	60[4]	–	4.6	3.1[2]	5.7	5.7	Internal secondary part to accessible outer enclosure (Only for power adapter model)
K	2MOPP	IIIb	Max. 48Vdc	–	--	--	--	--	Accessible parts per 8.4.2 c)

Supplementary Information:

1) **The same area is evaluated in open frame model. And there is no more difference if not specified.**
2) **Multiplication factor for MOOP: 1.48; Multiplication factor for MOPP: 1.29.**
3) **Minimum 0.4 mm thick Mylar sheet or two layers of insulating tape wrap around internal conductive parts along the enclosure joint. This method is applied only to the model sold to high elevation region. Otherwise, the clearance and creepage distance is measured as 5.7/5.7 mm.**
4) **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.**
5) **Linear interpolation is applied to the determination of required creepage.**
6) **The minimum creepage and clearance is selected from all the types of optocouplers.**
7) **The bottom of ferrite core is wrapped around 2 layers of insulating tape.**
8) **Two layers of insulating tape or two layers of insulating tube wrap around the heatsink.**
9) **Creepage shall not be less than Clearance.**

INSULATION DIAGRAM CONVENTIONS and GUIDANCE:

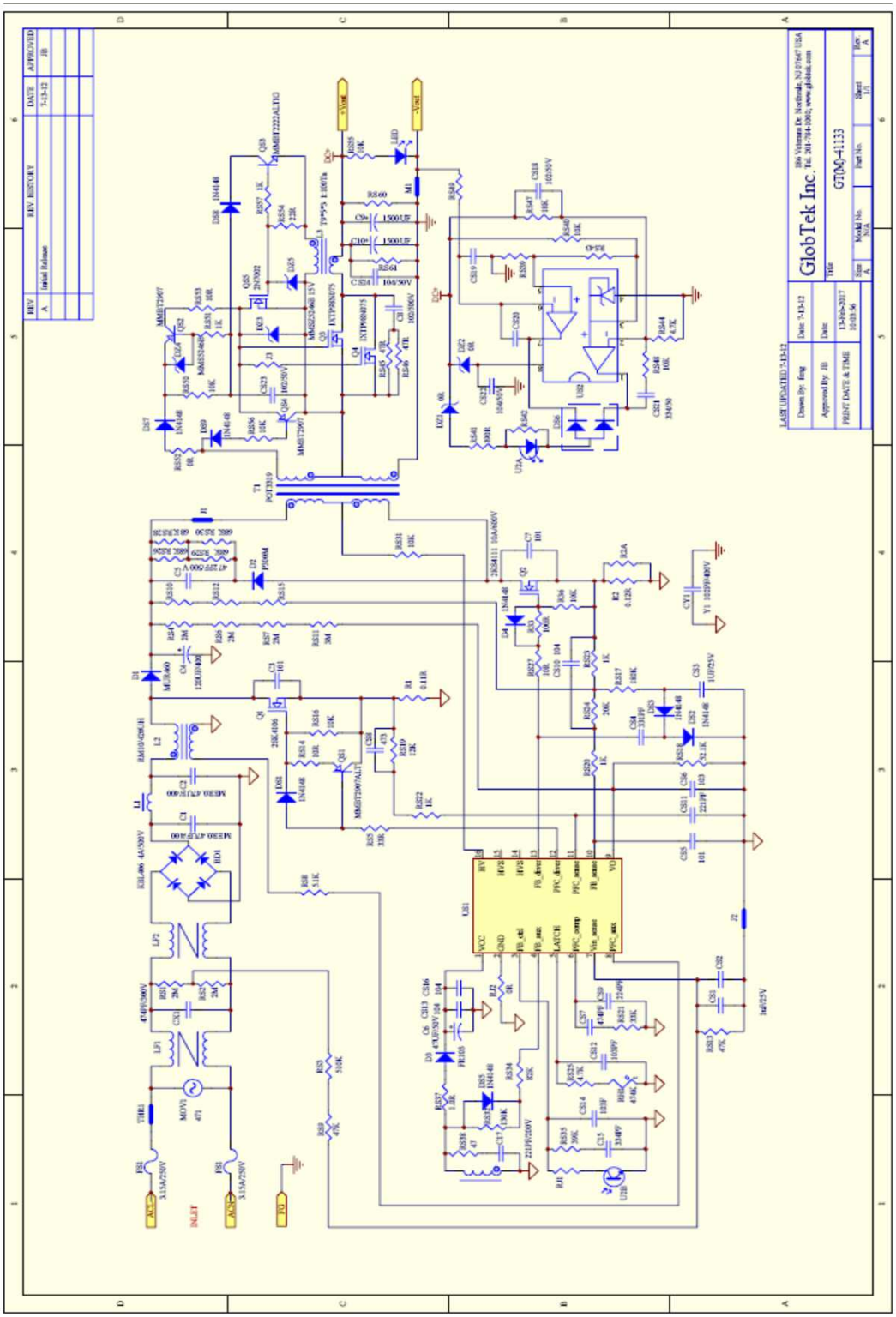
A measured value must be provided in the value columns for the device under evaluation. The symbol > (greater than sign) must not be used. Switch-mode power supplies must be re-evaluated in the device under evaluation therefore N/A must not be used with a generic statement that the component is certified.

Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:

- All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.
- Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional
- Applied parts are extended beyond the equipment enclosure and terminated with an arrow.
- Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.

7.0 Illustrations

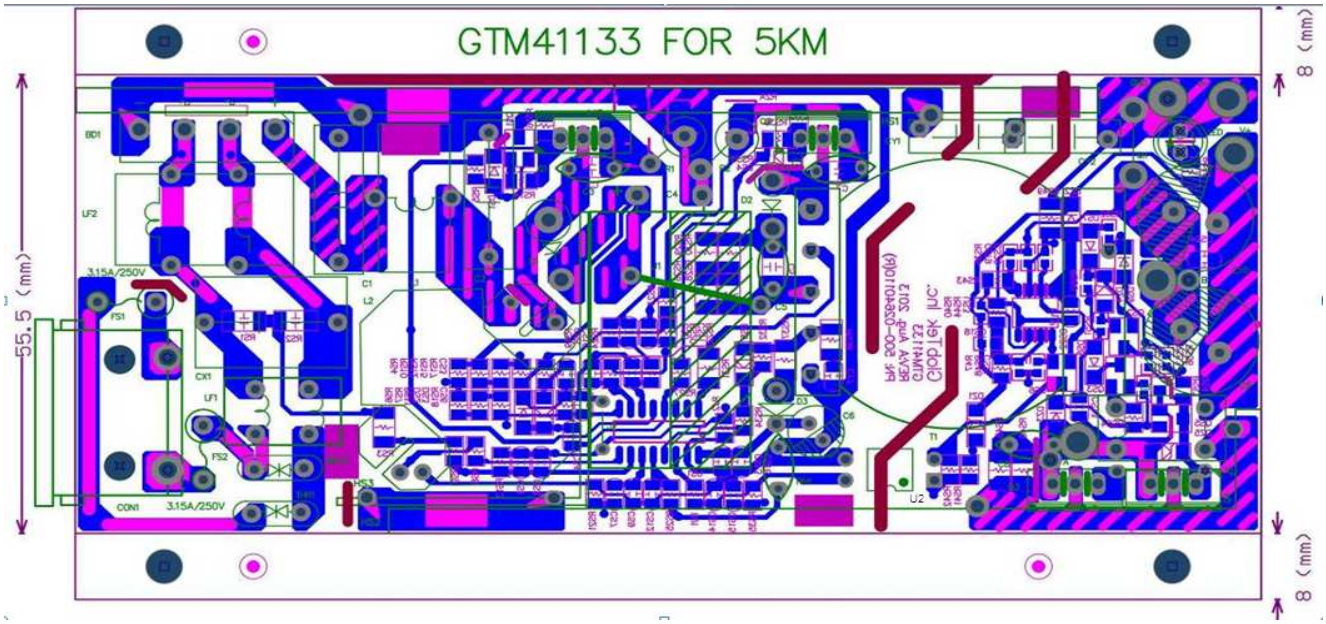
Illustration 4 - GT*41133 series Schematics



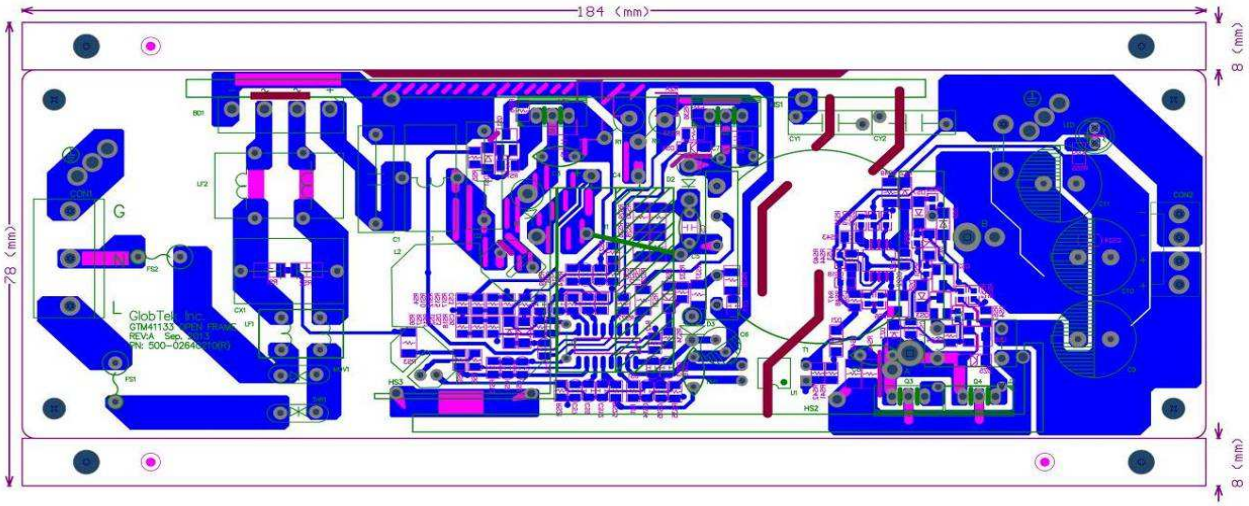
7.0 Illustrations

Illustration 5 - GT*41133 series PCB LAYOUT

PCB layout for adapter model



PCB layout for open frame model

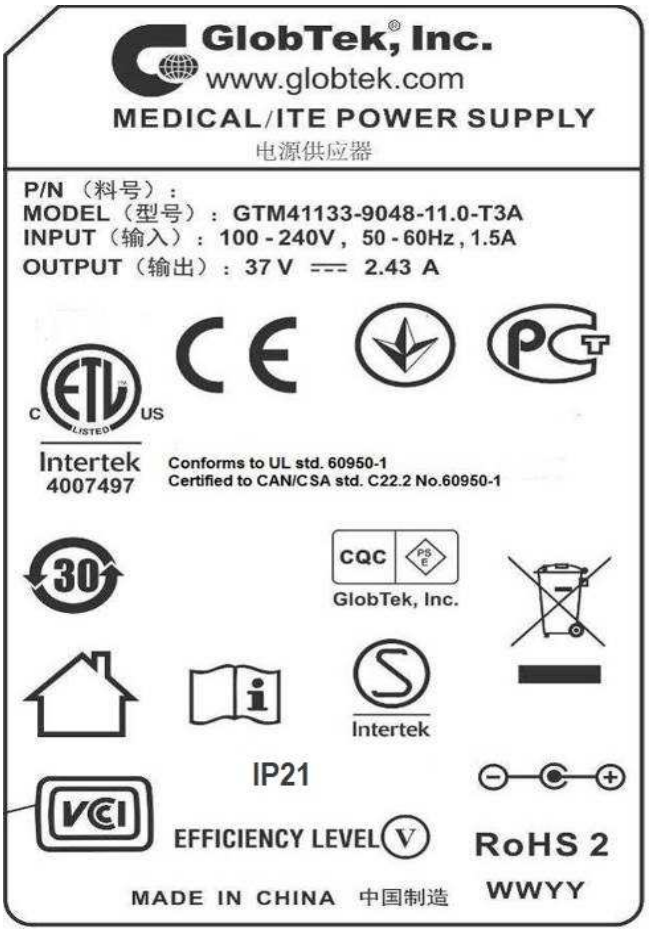


7.0 Illustrations

Illustration 6 - Marking label

The marking plates of the other models listed in this report are identical with below except model name and output parameter.

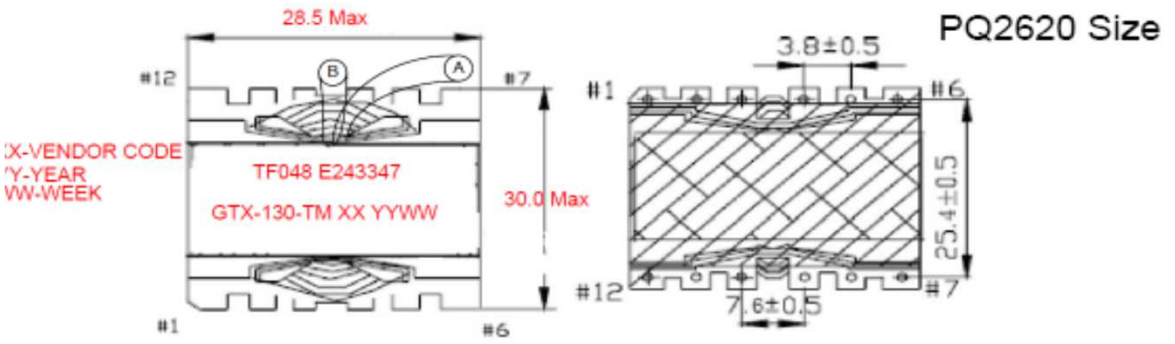
Note: For power adapter model, the left one represents Class I model series & the right one represents Class II model series. Only Class II adapter models were evaluated by 60601-1-11.

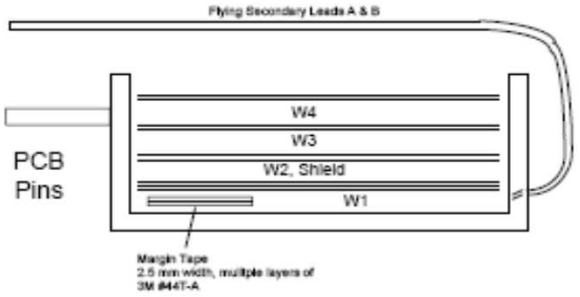


Marking plate of open frame model

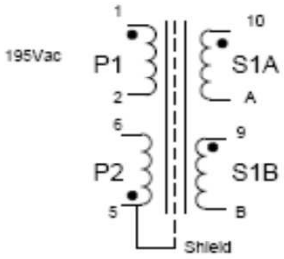
7.0 Illustrations

Illustration 7 - GT*41133 series Mains transformer specification





Bobbin pins 3, 4, 11 and 12 removed



W1: Secondary coil, bifilar wound (S1A & S1B)
(winding must be as pair, together)
Insulation tape, 3 turns, W = 9.5mm, T = 0.025mm

W2: Shield, 1.1 turn, must be fully cuffed (insulated)

Insulation tape, 2 turns, W = 9.5mm, T = 0.025mm

W3: Main Primary (P1), (2 Layers)

Insulation tape, 2 turns, W = 9.5mm, T = 0.025mm

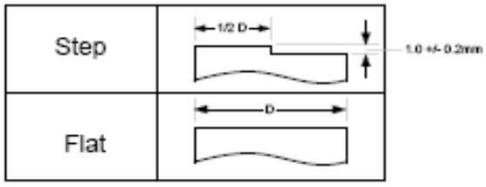
W4: Vcc Primary (P2)

Insulation tape, 2 turns, W = 9.5mm, T = 0.025mm

A & B Flying Wires

CUFFING INSTRUCTIONS
SHOWN ON PAGE 2

Gap Option for Improved Inductance Repeatability



7.0 Illustrations

Illustration 8 - GT*41133 series Mains transformer specification (cont.)

3. ELECTRICAL CHARACTERISTICS

NO	ITEM	TERMINAL	SPECIFICATION	REMARKS
3-1	INDUCTANCE	1-3	475uH±10%	GainKaiTa3250 @30KHz,1Vrms
3-2	LEAK INDUCTANCE	1-3 短路其他绕组	25uH MAX	
3-3	HI-POT TESTING	Pri-Sec	AC 3.75KV/2mA/3S	CJ2670
		Pri-Core	AC 1.5KV/2mA/3S	
		Sec-Core	AC 1.5KV/2mA/3S	

4. WINDING SPEC

NO	TERMINAL		TURNS	WIRE	STRANDS	INSULATION MATERIAL	INSULATION LAYERS
	S	F					
N1	1	2	26	2UEW/130 φ0.10	25	PET 0.025	2
E1	5		0.9	0.05*7W(背胶)		PET 0.025	2
N2	CT1	CT2	11	TRWB φ0.55	2	PET 0.025	2
N3	4	5	8	2UEW/130 φ0.22	2	PET 0.025	2
N4	2	3	12	2UEW/130 φ0.10	25	PET 0.025	2

1. N1 绕组需层间绝缘。
2. N3 疏绕一层。
3. N2 均为飞线引出，CT1 穿透明套管，从 PIN6 脚侧旁进线。CT2 穿黑色套管，从 PIN9,10 脚间出线。

7.0 Illustrations

Illustration 9 -GT*961200P***** series and GT*96900P***** series TABLE: Insulation diagram (measured values)

TABLE: INSULATION DIAGRAM		P
Pollution degree ..... :	2	—
Overvoltage category ..... :	II	—
Altitude ..... :	Up to 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	–	3.0[9]	3.0[2]	3.6	3.6	Opposite polarity of mains part
B	MOPP	IIIb	240	340	4.0	3.3[2]	6.2	6.2	Mains parts to PE terminal (Along PCB trace)
C	2MOPP	IIIb	240[4]	–	7.9[5]	6.5[2]	8.0[3]	8.0[3]	Internal mains part to accessible outer enclosure (Only for power adapter model)
D	2MOPP	IIIb	240[4]	–	7.9[5]	6.5[2]	8.0[8]	8.0[8]	Mains parts to secondary pin-out (Optocoupler)
E	2MOPP	IIIb	277[4]	–	9.1[5]	9.1[2]	11.7[7]	11.7[7]	Secondary side (including ferrite) to primary pin-outf (Transformer)
F	MOPP	IIIb	240[4]	–	4.0[5]	3.3[2]	5.4	5.4	Primary side to secondary side (CY1)
F[1]	MOPP	IIIb	240[4]	–	4.0[5]	3.3[2]	4.4	4.4	Primary side to secondary side (CY2)
G	2MOPP	IIIb	277[4]	–	9.1[5]	9.1[2]	11.0	11.0	Mains parts to secondary parts (Nearest points along PCB trace)
H	2MOPP	IIIb	240[4]	–	7.9[5]	6.5[2]	10.0[8]	8.0[3]	Primary heatsink to secondary circuit
I	2MOPP	IIIb	240[4]	–	7.9[5]	6.5[2]	10.0[8]	10.0[8]	Primary circuit to secondary heatsink
J	2MOPP	IIIb	60[4]	–	4.6	3.1[2]	6.7	6.7	Internal secondary part to accessible outer enclosure (Only for power adapter model)
K	2MOPP	IIIb	Max. 48Vdc	–	–	–	–	–	Accessible parts per 8.4.2 c)

Supplementary Information:

1) **The same area is evaluated in open frame model. And there is no more difference if not specified.**
2) **Multiplication factor for MOOP: 1.48; Multiplication factor for MOPP: 1.29.**
3) **Minimum 0.4 mm thick Mylar sheet or two layers of insulating tape wrap around internal conductive parts along the enclosure joint. This method is applied only to the model sold to high elevation region. Otherwise, the clearance and creepage distance is measured as 5.7/5.7 mm.**
4) **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.**
5) **Linear interpolation is applied to the determination of required creepage.**
6) **The minimum creepage and clearance is selected from all the types of optocouplers.**
7) **The bottom of ferrite core is wrapped around 2 layers of insulating tape.**
8) **Two layers of insulating tape or two layers of insulating tube wrap around the heatsink.**
9) **Creepage shall not be less than Clearance.**

INSULATION DIAGRAM CONVENTIONS and GUIDANCE:

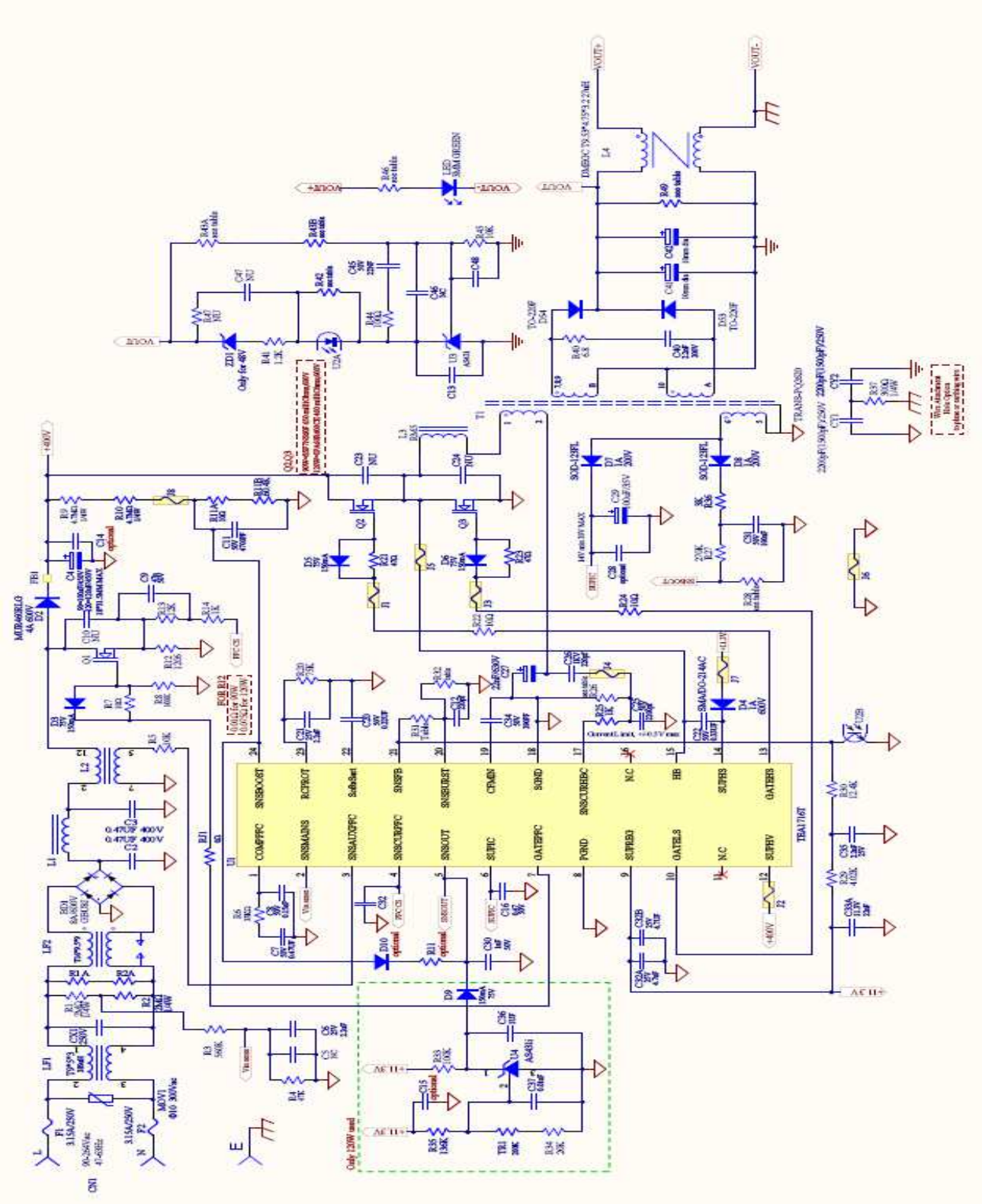
A measured value must be provided in the value columns for the device under evaluation. The symbol > (greater than sign) must not be used. Switch-mode power supplies must be re-evaluated in the device under evaluation therefore N/A must not be used with a generic statement that the component is certified.

Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:

- All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.
- Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional
- Applied parts are extended beyond the equipment enclosure and terminated with an arrow.
- Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.

7.0 Illustrations

Illustration 10 - GT*961200P*** series and GT*96900P***** series Schematics**



7.0 Illustrations

Illustration 11 - GT*961200P*** series and GT*96900P***** series PCB LAYOUT**

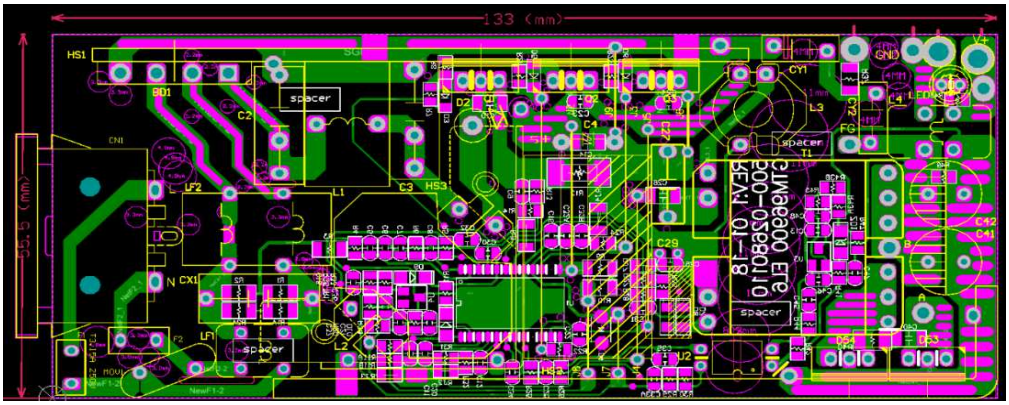
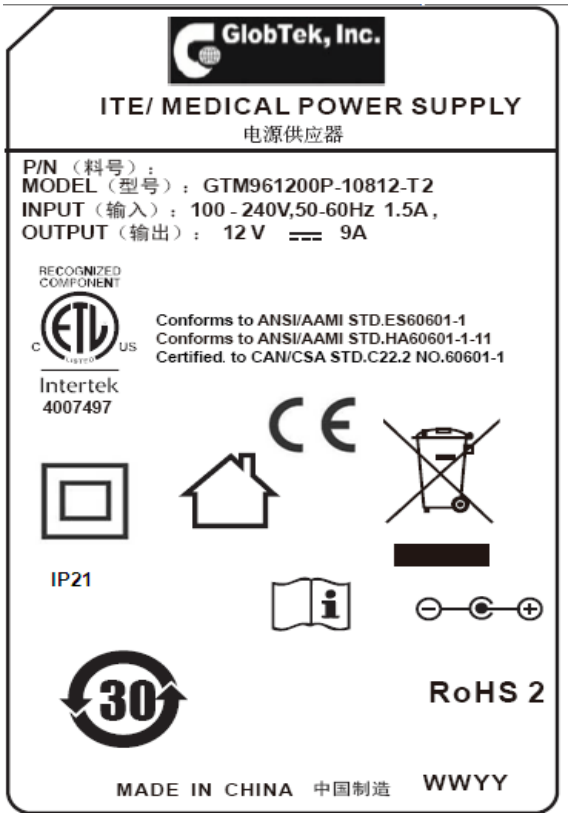
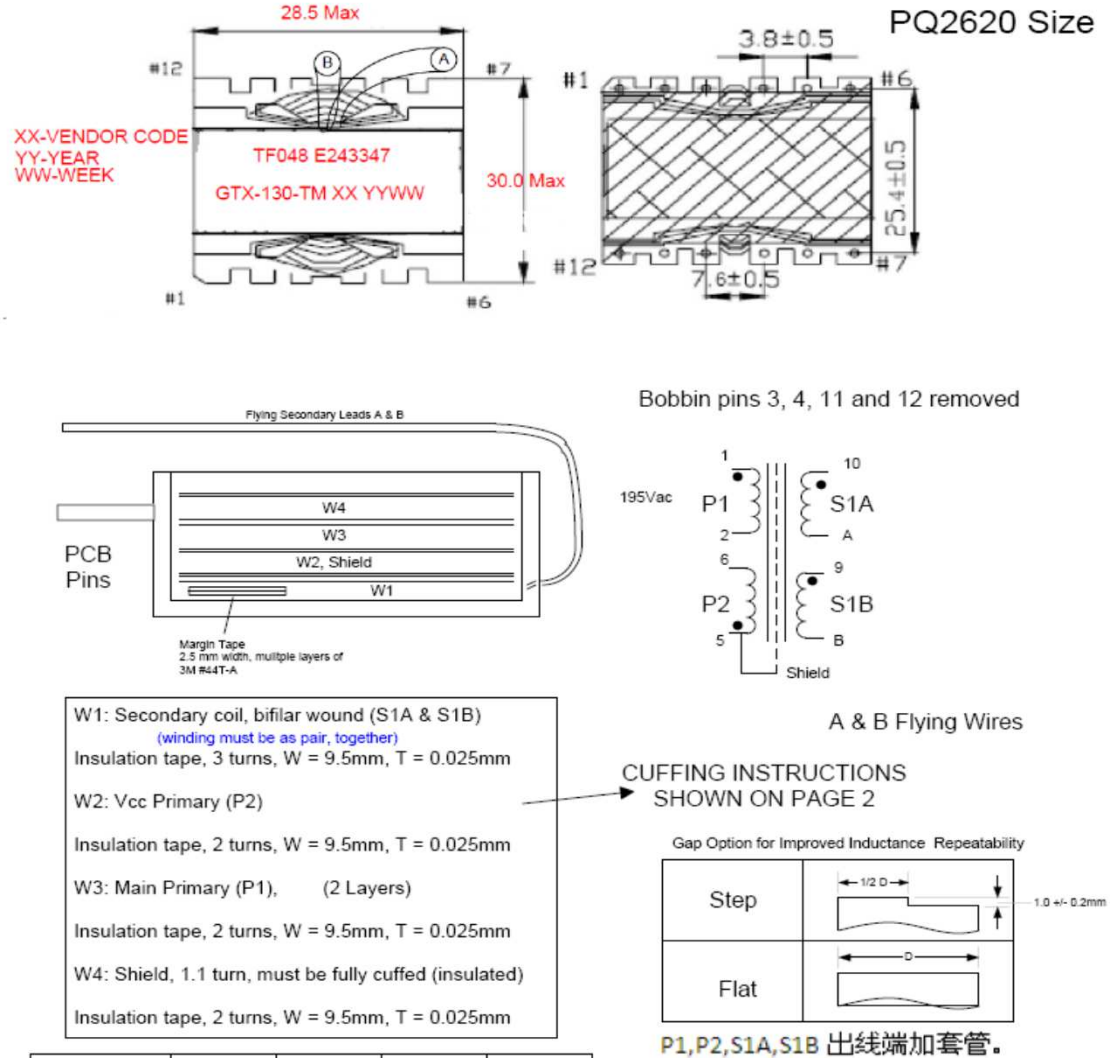


Illustration 12 - Marking label
The marking plates of the other models listed in this report are identical with below except model name name and output parameter.
Note: For power adapter model, the left one represents Class I model series & the right one represents Class II model series. Only Class II adapter models were evaluated by 60601-1-11.



7.0 Illustrations

Illustration 13 - GT*961200P*** series and GT*96900P***** series Mains transformer specification**



8.0 Test Summary					
Evaluation Period	2013-09-02~2013-09-29			Project No.	130801751SHA
Sample Rec. Date	2-Sep-2013	Condition	Prototype	Sample ID.	0130902-24-001/002/003
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:					

Test Description	Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance (ANSI/AAMI ES60601-1 Issued: 2006/03/09: 2005 Version (R2012); with AMD C1: 2009, AMD C2: 2010 & CAN/CSA-C22.2 No.60601-1 Issued: 2008/02/01; with COR 2: 2011/06/01) 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
Excessive Temperature	11.1
Single Fault Conditions	13.2
Push Test	15.3.2
Impact Test	15.3.3
Drop Test	15.3.4
Moulding Stress Relief	15.3.6
Transformer Short-Circuit	15.5.1.2
Transformer Overload	15.5.1.3
Transformer Dielectric Strength	15.5.2

Test Description	Medical 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 (ANSI/AAMI HA60601-1-11 Issue:2011/12/12 Ed:1) Clause
Environmental conditions of transport and storage between uses	4.2.1
Environmental operating conditions	4.2.2
Shock test	10.1.2 a)
Vibration test	10.1.2 b)

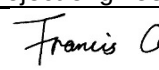
Evaluation Period	2016-12-26 to 2017-03-17			Project No.	161200818SHA
Sample Rec. Date	26-Dec-2016	Condition	Prototype	Sample ID.	--
Test Location	Building No.86, 1198 Qinzhou Road (North), Shanghai 200233, China				
Test Procedure	Testing Lab				
Determination of the result includes consideration of 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:					

8.0 Test Summary	
Test Description	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (R2012) [AAMI ES60601-1:2005 +C1;A2] 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
Excessive Temperature	11.1
Single Fault Conditions	13.2
Push Test	15.3.2
Impact Test	15.3.3
Drop Test	15.3.4
Moulding Stress Relief	15.3.6
Transformer Short-Circuit	15.5.1.2
Transformer Overload	15.5.1.3
Transformer Dielectric Strength	15.5.2

Test Description	Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety & Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment & Medical Electrical Systems Used In The Home Healthcare Environment [AAMI HA60601-1-11:2015 Ed.2] Clause
Environmental conditions of transport and storage between uses	4.2.1
Environmental operating conditions	4.2.2
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:	Francis Cai	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 USA
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. Dansy Xu
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
All products covered by this Report:		
Between L/N and PE terminal for Class I models only	1500V	1 s
Between L/N and secondary output for Class II models only	4000V	1 s

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
17-Apr-2017		1.0	Std.	Updated the standard from "Medical electrical equipment, Part 1: General requirements for basic safety and essential performance (ANSI/AAMI ES60601-1 Issued: 2006/03/09: 2005 Version (R2012); with AMD C1: 2009, AMD C2: 2010 & CAN/CSA-C22.2 No.60601-1 Issued: 2008/02/01; with COR 2: 2011/06/01); 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 (ANSI/AAMI HA60601-1-11 Issue:2011/12/12 Ed:1)." to "Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (R2012) [AAMI ES60601-1:2005 +C1;A2] Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance [CSA C22.2#60601-1:2014 Ed.3] Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety & Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment & Medical Electrical Systems Used In The Home Healthcare Environment [AAMI HA60601-1-11:2015 Ed.2] "
		2.0	Models	Updated the model from " GT*41133-***-** " to " GT*41133-***-**, GT*961200P***** and GT*96900P*****
		2.0	Model similarity	Updated the model similarity for GT*41133-***-**, GT*961200P***** and GT*96900P*****
		2.0	Ratings	Updated the ratings from "Input: 100-240V~, 50-60Hz, 1.5A; Output: Refer to illustration No.1 for details. " to "GT*961200P**** and GT*96900P****, Input:100-240V~,50-60Hz, 1.5A; GT*41133-*****,Input:100-240V~, 50-60Hz or 50-400Hz, 1.5A; Output: Refer to illustration No.1 for details. "
		3.0	15 - 38	Add new photos for GT*961200P***** and GT*96900P*****
		4.0	1	Added alternative plastic enclosures as "Manufacturer - SABIC INNOVATIVE PLASTICS B V", "Type - SE100", "Technical data - PPE+PS, Min. V-1, Min. thickness: 2.0mm, 95°C", and as "Manufacturer - SABIC INNOVATIVE PLASTICS B V", "Type - C2950", "Technical data - PC/ABS, Min. V-0, Min. thickness: 2.0mm, 85°C", and as "Manufacturer - SABIC INNOVATIVE PLASTICS B V", "Type - 945", "Technical data - PC, Min. V-1, Min. thickness: 2.0mm, 120°C". Updated the min. thickness for all materials of enclosures from "1.5mm" to "2.0mm".

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	2	Added alternative AC inlet as "Manufacturer - Zhe Jiang Bei Er jia", "model - ST-A03-005", "Technical data - 2.5A, 250Vac Standard sheet: C8". Added new alternative AC inlet while the technical data were "10A, 250Vac Standard sheet: C14" as "Manufacturer - Zhejiang LECI Electronics Co., Ltd., Model - DB-14" & "Manufacturer - Rich Bay Co., Ltd., Model - R-301SN" & "Manufacturer - Sun Fair Electric Wire & Cable (HK)Co. Ltd., Model - S-03" & "Munufacturer - TECX-UNIONS Technology Corporation, Model - TU-301-S,TU-301-SP" & "Manufacturer - Rong Feng Industrial Co., Ltd., Model - SS-120" & "Manufacturer - Inalways Corporation - Model - 0711" & " Manufacturer - Zhe Jiang Bei Er jia, Model - ST-A01-003J". Added new alternative AC inlet while the technical data was "10A, 250Vac Standard sheet: C18", as "Manufacturer - Rong Feng Industrial Co.,Ltd", "Model - SS-120".
		4.0	3	Deleted alternative output cords where manufacturer was "ZHUANG SHAN CHUAN ELECTRICAL PRODUCTS (KUNSHAN) CO LTD", "ZHUANG SHAN CHUAN ELECTRICAL PRODUCTS (KUNSHAN) CO LTD", "SUZHOU YEMAO ELECTRONIC CO LTD", or "SUZHOU DIOUDE ELECTRONICS CO LTD"
		4.0	4	Added alternative manufacturer, "DONGGUAN GUNEETAL WIRE & CABLE CO LTD" & "KUNSHAN XINGHONGMENG ELECTRONIC CO LTD". Deleted alternative manufacturer, "SUZHOU HONGMENG ELECTRONIC CO LTD". Updated "Type/model" for all manufacturer from "1015 1007" to "1015,1007,1185"
		4.0	6	Added alternative PCB material as "Manufacturer - WALEX ELECTRONIC (WUXI) CO LTD", "Model - T2". Deleted alternative PCB material which "Manufacturer - TECHNI TECHNOLOGY LTD", "Model - T2A, T2B, T4". Update the model of alternative PCB material from "DKV0-3A" to "DKV0-3A, DGV0-3A " where the manufacturer was "BRITE PLUS ELECTRONICS (SUZHOU) CO LTD "

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
161200818SHA	Francis Cai / Justin Yu	4.0	7	Deleted alternative fuses which manufacturer were "Walter Electronic Co. Ltd.", "Sun Electric Co.", "Bel Fuse Ltd." or "Das & Sons International Ltd." Added alternative fuses as "Manufacturer - Dongguan Better Electronics Technology Co., Ltd., model - 932, technical data - T3.15A, 250Vac, interrupting rating 100A", "Manufacturer - Hollyland Company Limited, model - 5ET, technical data - T3.15A, 250Vac, interrupting rating 63A", "Manufacturer - Sunny East Enterprise Co. Ltd., model - CFD, technical data - T3.15A, 250Vac, interrupting rating 50A" and "Manufacturer - Conquer Electronics Co., Ltd., modle - MET, technical data - T3.15A, 250Vac, interrupting rating 35A"
		4.0	8	Deleted alternative varistor which manufacturer was "HONGZHI ENTERPRISES LTD ". Added alternative varistor as "Manufacturer - Walsin Technology Co., Ltd.", "Model - 14D471K". Updated the modle of alternative varistor where manufacturer was "LIEN SHUN ELECTRONICS CO LTD " from "07D471K, 10D471K,14D471K " to "14D471K ". Deleted the model, which contains "07", of all alternative varistors
		4.0	9	Updated the capacitor fo all alternative X capacitor from "Max. 0.47µF" to "(For GT*96900 series, GT*961200 series: Max. 0.22µF), (For GT*41133 series: Max. 0.47µF)". Corrected the manufacturer form "Shunde Da Hua Electric Co., Ltd." to "Foshan Shunde Beijiao Hua Da Electric Industrial Co., Ltd.", where the model was "HD-MKP". Added 2 alternative X capacitor as "Manufacturer - Jiangsu Xinghua Huayu Electronics Co., Ltd., Model - MPX, technical date - (For GT*96900 series, GT*961200 series: Max. 0.22µF), (For GT*41133 series: Max. 0.47µF), 275Vac, 100°C, type X2 " and "Manufacturer - Shenzhen Jinghao Capacitor Co., Ltd., model - CBB62B, technical data - (For GT*96900 series, GT*961200 series: Max. 0.22µF) (For GT*41133 series: Max. 0.47µF) 250Vac or 280Vac or 305Vac, 110°C, type X2 "
		4.0	11	Updated the model of "Line Filter (LF2)" from "LF002" to "LF002 (For model:GT*41133 series), LF026 (model:GT*96900P series, GT*961200P series)"

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	12	updated the name of item 12 from "Line filter (LF3)" to "Line filter (LF3 For model:GT*41133 series) (L1 For model:GT*96900 series, GT*961200 series)"
		4.0	13	Updated the model of "PCF Chock (L2)" from "LF004" to "LF004(For model:GT*41133 series) , LF028 (model:GT*96900P series, GT*961200P series)"
		4.0	14	Added 2 alternative Y capacitor as "Jyh Chung Electronic Co., Ltd., Model - JD" and "WELSON INDUSTRIAL CO LTD, Model - WD"
		4.0	15	Updated the optocoupler which manufacturer was "LITE-ON Technology Corporation " from "Model - LTV-817C , technical data - Ext. Cr: min. 8.0 mm; DTI: min. 0.6 mm; Thermal cycling test. Max. operating temp.: 115°C, mark - CB" to "Model - LVT-817, technical data - isolation voltage 5300Vrms, mark - cURus". Updated the optocoupler which manufacturer was "Everlight Electronics Co., Ltd. " from " technical data - Ext. Cr: min. 7.7 mm; DTI: min. 0.5 mm; Thermal cycling test. Max. operating temp.: 110°C, mark - CB" to "technical data - isolation voltage 5000Vrms, mark - cURus".
		4.0	16	Added alternative transformer for GT*96900 series and GT*961200 series as "Model - TF047 TF075, TF048, TF076, TF072, TF077, TF049, TF078 TF073, TF079, TF050, TF074", "technical data - Class B, with insulation system and critical component listed below. Refer to illustration No. 13 for Spec."
		4.0	16b	Added an alternative magnet wire (primary) as "Manufacturer - PACIFIC ELECTRIC WIRE & CABLE (SHENZHEN) CO LTD", "Model - UEWS/U"
		4.0	16e	Added 3 alternative triple-insulated wire (secondary winding) as "Manufacturer - CHANGYUAN ELECTRONICS (SHENZHEN) CO LTD, Model - CB-TIW ", "Manufacturer - E&B TECHNOLOGY CO LTD, Model - E&B-XXXB,E&B-XXXB-1" and "Manufacturer - TOTOKU ELECTRIC CO LTD, Model - TIW-2"
		4.0	16f	Added item for PTFE tubing as "Manufacturer - Great Holding Industrial Co Ltd, Model - TFT / TFS, Technical data - Min. 300V, 200°C", "Manufacturer - Changyuan Electronics (Shenzhen) Co Ltd, Model - CB-TT-T, CB-TT-S, Technical data - Min. 300V, 200°C" and "Manufacturer - Shenzhen Woer Heat-Shrinkable Material Co Ltd, Model - WF, Technical data - 600V, 200°C"
		4.0	17	Added alternative mylar insulating sheet as "Manufacturer - CHENGDU KANGLONGXIN PLASTICS CO LTD", "Model - KLX FRPC-1860B ", "Technical data - VTM-0, Min. 0.4mm thickness, 80°C"

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
		6.0	8	Update the reference illustration No. for schematics from "4-5" to "4-5 & 10-11"
		6.0	9	Update the reference illustration No. for Markings from "6" to "6 & 12"
		6.0	10	Update the reference illustration No. for Catutionary Markings from "6" to "6 & 12"
		7.0	---	Updated illustration 1, 3, 5, 6; Added illustration 9 to 13 for GT*961200P***** and GT*96900P*****
		8.0	---	Added new test block according to "Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (R2012) [AAMI ES60601-1:2005 +C1;A2] Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance [CSA C22.2#60601-1:2014 Ed.3] "
		8.0	---	Added new test block according to "Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety & Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment & Medical Electrical Systems Used In The Home Healthcare Environment [AAMI HA60601-1-11:2015 Ed.2] "
		8.1	---	Revised with new signature
		11.0	---	Added the decription for products which requiring dielectric voltage withstand test as "All products covered by this Report:"