

RECOGNIZED COMPONENT Constructional Data Report (CDR)

1.0 Reference and Address								
Report Number	151100934SHA-001	Original Issued:	25-Dec-2015	Revised: None				
		AAMI ES60601-1 Issued: 2012/08/20 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance, Amendment 1						
Standard(s)	CAN/CSA-C22.2 No.60601-1:14, Third Edition Issued: 2014/03/01 - Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance							
IEC 60601-1-11 Issued: 2015/01/20 Ed. 2 Medical Elec. Equip Part 1-11: Gen. R Safety & Essential Perf Collateral Standard - Req. for Medical Elec. Equip. & Me Systems Used in the Home Healthcare Environment								
Applicant	GlobTek, Inc.		Manufacturer	GlobTek (Suzhou) Co., Ltd.				
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2.0 Product Description Medical Power Supply Product GlobTek, Inc. 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 four structure types respectively. First structure is direct plug-in power adapter with interchangeable plug portion, which is Class II apparatus. It can be used with different plug types. The evaluation reports of the different plug types are also attached with this report. Two pieces of outer enclosure are enclosed with ultrasonic welding without screw. Second structure is open frame type which also provides a protective earth bonding terminal on the PCB. Interchangeable appliance inlets can be mounted on the device, which can provide earthing connection or not. The installation and use for the insulation construction shall be finally determined in the end product. Description Third structure Model GT-41134-0606-W2-TAB is special direct plug-in type for North America market, with particular housing, varistor and fixed NEMA 1-15P plug. Fourth structure is used in model series GT*41134****** and GT*96060******, it use F1 fuse in primary circuit and a LED indicator (optional) used in secondary circuit. 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. This product should be purchased together with the end equipment, it can not be sold separately. Altitude: less than 5000m GT*41134****** Models GT*96060***** GT-41134-0606-W2-TAB GT*41134***** and GT*96060****** The 1st "*" part can be 'M' or '-' or 'H' for market identification and not related to safety. The 2nd "*" part can be "-" or "CC","-" = Constant Voltage Model, CC = Constant Current Model. The 3rd "*" denotes the rated output wattage designation, which can be "01" to "06", with interval of 1. The 4th "*" denotes the standard rated output voltage designation, which can be "03", "04", "06", " 12", "15", "18", "24", "36" or "48". The 5th "*" is optional deviation, subtracted from standard output voltage, which can be "-0.1" to "-11.9" with interval of 0.1, or blank to indicate no voltage different. The 4th "*" and 5th "*" together denote the output voltage, with a range of 3.3 - 48 volts. The 6th "*" =Blank means directly plug in model series, = "-F" means Class I open frame model with connector which is fixing on the PCB, = "-FW" means Class II open frame model with connector which is fixing on the PCB. ="-FWT2" means open frame model with appliance inlet with Class II inlet C8 respectively, Model Similarity ="-FT3A" means open frame model with appliance inlet with Class I inlet C6 respectively, ="-FT3" means open frame model with appliance inlet with Class I inlet C14 respectively, The last * denote any six character = 0-9 or A-Z or ()[] or – or blank for marketing purposes. Test performed on 3.3V, 5V, 9V and 48V output model as worst condition, and also performed on this component when installed in the end product. GT*96060***** is identify with GT*41134***** except for model name. GT*96060***** and GT*41134***** were evaluated for maximum manufacturer's recommended ambient of 50 °C.GT-41134-0606-W2-TAB was evaluated for maximum manufacturer's recommended ambient of 50 °C. Input: 100-240V \sim , 50-60Hz, 0.3A or 0.6A for GT*41134***** and GT*96060****** Ratings 120V~, 60Hz, 0.3A for GT-41134-0606-W2-TAB Output: Refer to illustration No.1 for details. Other Ratings

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2.0 Product Description

The products covered in this Report are incomplete in construction features or limited in performance capabilities and are intended for use and evaluation in other products. Consideration should be given to the following when the component is used in or with another product.

- 1. Scope of Power Supply evaluation defers the following clauses to be determined as part of the end product investigation:
- a) Clause 7.9 (Accompanying Documents of power adapter model are provided for some critical issue like technical data, safety warnings, necessary information to set up. Further evaluation is needed for both power adapter model and open frame model on end product level.),
- b) Clause 8.11.5 (Mains Fuse with High Breaking Capacity),

Conditions of Acceptability

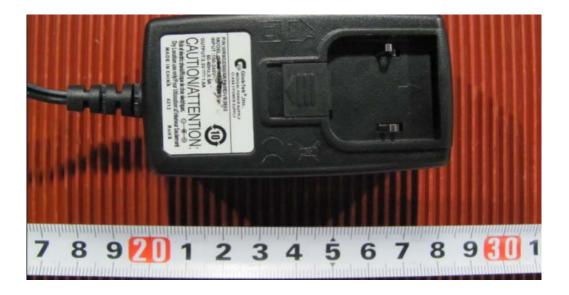
- c) Clause 9 (ME Hazard), except 9.1 and 9.3 are evaluated,
- d) Clause 10 (Radiation),
- e) Clause 11.7 (Biocompatibility),
- f) Clause 14 (PEMS),
- g) Clause 16 (ME Systems),
- h) Clause 17 (EMC)
- 2. For open frame model
- Suitability of the enclosure should be evaluated when installed in the end product including access to energized parts, clearance & creepage distance measurement and mechanical strength.
- Temperature Testing should be performed on this component when installed in the end product.

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PHOTO 1 - EXTERNAL VIEW – 1 OF ADAPTER MODEL GT*41134******(First structure)



PHOTO 2 - EXTERNAL VIEW OF ADAPTER MODEL GT*41134******(First structure)



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PHOTO 3 - EXTERNAL VIEW OF ADAPTER MODEL GT*41134******(First structure)



PHOTO 4 - INTERNAL VIEW OF ADAPTER MODEL GT*41134******(First structure)



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PHOTO 5 - COMPONENT SIDE VIEW OF PCB OF ADAPTER MODEL GT*41134****** (First structure)



PHOTO 6 - SOLDERING SIDE VIEW OF PCB OF ADAPTER MODEL GT*41134******(First structure)

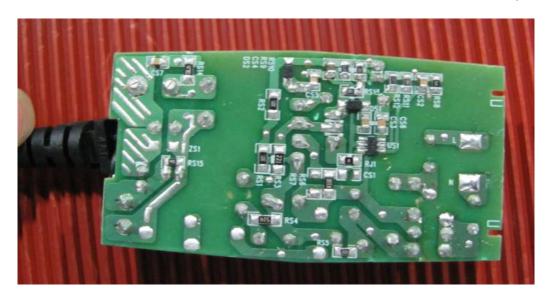
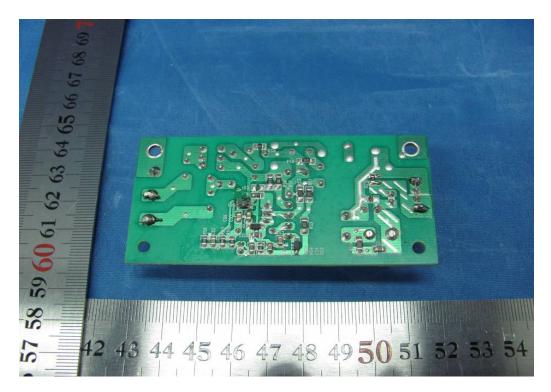


PHOTO 7 - COMPONENT SIDE VIEW OF OPEN FRAME MODEL(Second structure)



PHOTO 8 - SOLDERING SIDE VIEW OF OPEN FRAME MODEL (Second structure)



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PHOTO 9 - COMPONENT SIDE OF OPEN FRAME MODEL WITH APPLIANCE INLET(Second structure)

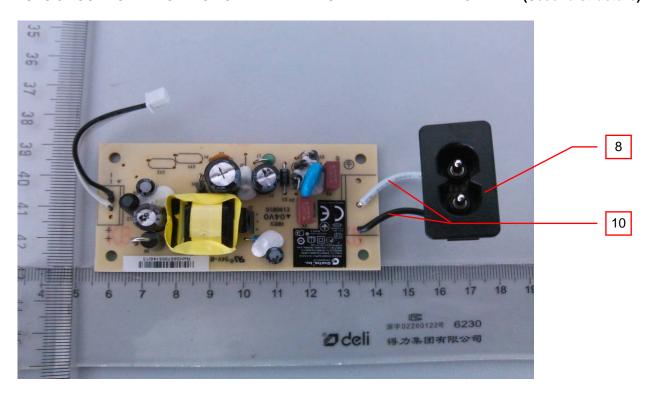


PHOTO 10 - SOLDERING SIDE OF OPEN FRAME MODEL WITH APPLIANCE INLET(Second structure)

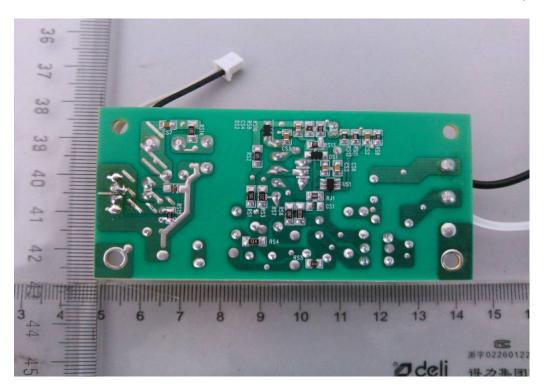


PHOTO 11 - EXTERNAL VIEW - 1 OF MODEL GT-41134-0606-W2-TAB(Third structure)



PHOTO 12 - EXTERNAL VIEW - 2 OF MODEL GT-41134-0606-W2-TAB(Third structure)



Photo 13 - Component side view of PCB of model GT-41134-0606-W2-TAB(Third structure)

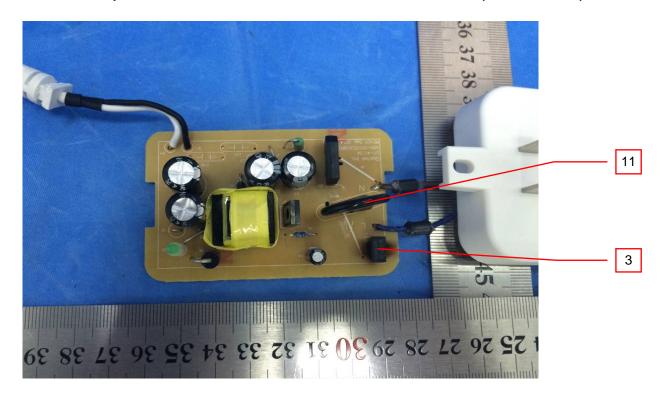
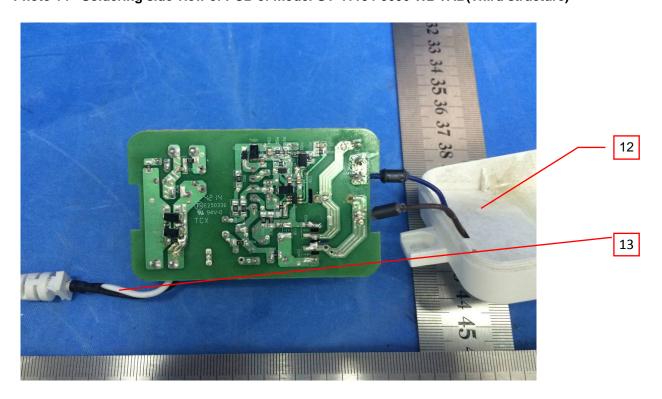


Photo 14 - Soldering side view of PCB of model GT-41134-0606-W2-TAB(Third structure)



3.0 Product Photographs

GlobTek, Inc.

Photo 15 - Plug pin side view of NEMA 1-15P plug portion

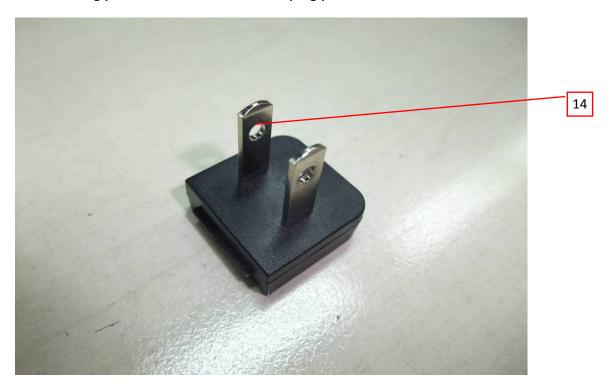


Photo 16 - Connector side view of NEMA 1-15P plug portion



Photo 17 - External view of adapter model GT*96060******(Fourth structure)



Photo 18 - Internal view of adapter model GT*96060******(Fourth structure)



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3.0 Product Photographs

GlobTek, Inc.

Photo 19 - Component side view of PCB of model GT*96060******(Fourth structure)

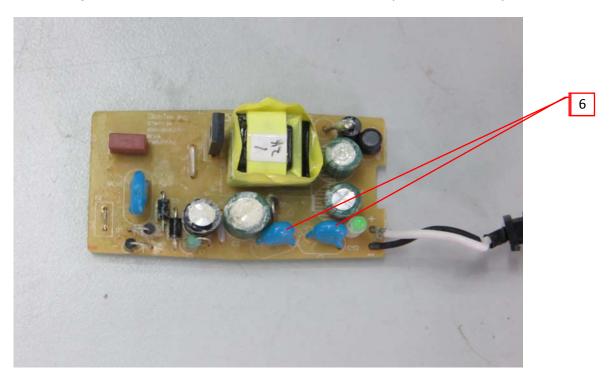


Photo 20 - Component side view of PCB of model GT*96060******(Fourth structure)



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 ³
			SABIC INNOVATIVE PLASTICS B V	SE1 SE1X 945	Min. V-1 at 1.5 mm thickness	
			SABIC INNOVATIVE PLASTICS B V	SE100	Min. V-1 at 2.0 mm thickness	
1	1	Enclosure & Blade holder	SABIC INNOVATIVE PLASTICS B V	C2950 CX721 EXCY0098 940	Min. V-0 at 2.0 mm thickness	cURus
			TEIJIN CHEMICALS LTD	LN-1250P LN-1250G	Min. V-0 at 2.0 mm thickness	
			CHI MEI CORP	PA-765A	Min. V-1 at 2.0 mm thickness	
			CHI MEI CORP	PC-540	Min. V-0 at 2.0 mm thickness	
			TECHNI TECHNOLOGY LTD	T2A T2B T4		
			DONGGUAN HE TONG ELECTRONICS CO LTD	CEM1 2V0 FR4		
			CHEERFUL	03		
			ELECTRONIC DONGGUAN DAYSUN ELECTRONIC CO LTD	03A DS2		
			SUZHOU CITY YILIHUA ELECTRONICS CO LTD	YLH-1		
5	2	PCB material	SHANGHAI AREX PRECISION ELECTRONIC CO LTD	04V0 02V0	Min. 1.6 mm thickness, min. V-0, 130°C	cURus
			BRITE PLUS ELECTRONICS (SUZHOU) CO LTD	DKV0-3A DGV0-3A		
			KUOTIANG ENT LTD	C-2 C-2A		
			PACIFIC WIN INDUSTRIAL LTD	PW-02, PW-03		
			TONGCHUANGXIN ELECTRONICS CO LTD	TCX		

Various

4.0 Critical Components Photo no.¹ Manufacturer/ Mark(s) of Technical data and Name Type / model² trademark² securement means conformity³ CONQUER T1A or T6.3A, 250V, Rated **MST ELECTRONICS CO LTD** breaking capacity 100A **EVER ISLAND** T1A or T6.3A, 250V, Rated 2010 ELECTRIC CO LTD & breaking capacity 130A T1A or T6.3A, 250V, Rated **RST** breaking capacity 100A **BEL FUSE INC** T1A or T6.3A, 250V, Rated 5ST breaking capacity 35A **COOPER BUSSMANN** T1A or T6.3A, 250V, Rated SS-5 breaking capacity 35A LLC Fuse⁴ (F1, F2) 3 DAS & SONS T1A or T6.3A, 250V, Rated 13 cURus 385T series (F2 is optional) INTERNATIONAL LTD breaking capacity 35A LANSON T1A or T6.3A, 250V, Rated SMT **ELECTRONICS CO LTD** breaking capacity 35A WALTER ELECTRONIC T1A or T6.3A, 250V, Rated ICP series CO LTD breaking capacity 50A. ZHONG SHAN LANBAO T1A or T6.3A, 250V, Rated **ELECTRICAL** RTI-10 series breaking capacity 50A APPLIANCES CO LTD T1A or T6.3A, 250V, Rated SUN ELECTRIC CO 5T breaking capacity 100A XF00716I for 3.3-4.9V XF00714I for 5-8.9V XF00717 for 9-14.9V XF00718 for 15-18.9V XF00719 for 19-24V Isolation /GlobTek/ BOAM/ XF00814 for Class B with insulation system 5 transformer NR 4 **HAOPUWEI** 24.1-36V below. (T1)XF00841 for 36.1-48V TF032 for 5-8.9V TF033 for 9-14.9V TF034 for 15-18.9V TF035 for 19-24V 130-1 GTX-130-TM Insulation **GLOBTEK INC** 5 5 system(not SHAN DONG BOAM Class B cURus BOAM-01 shown) ELECTRIC CO LTD

ZT-130

WUXI HAOPUWEI

ELECTRONICS CO LTD

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4.0 (Critic	al Components				
Р	Item		Manufacturer/		Technical data and	Mark(s) of
Photo #	no.1	Name	trademark ²	Type / model ²	securement means	conformity ³
	110.		liauciliaik			Cornornity
			TDK CORP	CD	Type Y1, max. 470pF, min.	
			SUCCESS	SE	250V, min. 125°C Type Y1, max. 470pF, min.	
			ELECTRONICS CO LTD		250V, min. 125°C	
				KX	Type Y1, max. 470pF, min.	
		Y-Capacitor	WALSIN TECHNOLOGY CORP	AH	250V, min. 125°C Type Y1, max. 470pF, min. 250V, min. 125°C	
19	6	(CY1 & CY2) (Optional) (Not	JYA-NAY CO LTD	JN	Type Y1, max. 470pF, min. 250V, min. 125°C	cURus
		shown)	HAOHUA ELECTRONIC CO	CT7	Type Y1, max. 470pF, min. 250V, min. 125°C	
			JERRO ELECTRONICS		Type Y1, max. 470pF, min.	
			CORP	JX-series	250V, min. 125°C	
			JYH CHUNG	JD	Type Y1, max. 470pF, min.	
			ELECTRONICS CO LTD	JD	250V, min. 125°C	
			WELSON INDUSTRIAL	WD	Type Y1, max. 470pF, min.	
			CO LTD		250V, min. 125°C	
			JOYIN CO LTD	07N471K		
				10N471K 14N471K		
			CENTRA SCIENCE	07D471K		
				10D471K		
				14D471K		
			THINKING ELECTRONIC	TVR07471K	1	
				TVR10471K		
		Varistor 7 (MOV1)	INDUSTRIAL CO LTD	TVR14471K		
			SUCCESS ELECTRONICS CO LTD	SVR07D471K	Maximum continuous voltage: 300Vac	
				SVR10D471K		
				SVR14D471K		
7	7		CERAMATE	GNR07D471K GNR10D471K		cURus
′	'	(Optional)	TECHNICAL CO LTD	GND14D471K		
		(Optional)		07D471K	1	
			BRIGHTKING	10D471K		
			CO LTD	14D471K		
			LIEN CLIUN	07D471K	1	
			LIEN SHUN ELECTRONICS CO LTD	10D471K		
			LLLG INDINICS CO LID	14D471K		
			HONGZHI	HEL-07D471K		
			ENTERPRISES LTD	HEL-10D471K		
				HEL-14D471K	-	
			GUANGXI NEW	07D471K		
			FUTURE INFORMATION	10D471K 14D471K		
		l	IINI OINIMITOIN	1404/ IN		

4.0 C	4.0 Critical Components									
Photo #	Item	Name	Manufacturer/	Type / model ²	Technical data and	Mark(s) of				
ð	no.1		trademark ²	. , , , , , , , , , , , , , , , , , , ,	securement means	conformity ³				
			Zhejiang LECI Electronics Co., Ltd.	DB-6						
			Rich Bay Co., Ltd.	R-30790 R-307						
			Sun Fair Electric Wire & Cable (HK)Co. Ltd.	S-02						
			TECX-UNIONS Technology Corporation	TU-333	2.5A, 250Vac Standard sheet: C6					
			Rong Feng Industrial Co., Ltd.	RF-190						
			Inalways Corporation	0724						
			Kunshan Dlk Electronics Technology Co., Ltd	CDJ-2						
			Zhejiang LECI Electronics Co., Ltd.	DB-14						
			Rich Bay Co., Ltd.	R-301SN	1	cURus				
9	8	AC inlet (Class	Sun Fair Electric Wire & Cable (HK)Co. Ltd.	S-03	10A, 250Vac					
		I or Class II)	TECX-UNIONS Technology Corporation	TU-301-S TU-301-SP	Standard sheet: C14					
			Rong Feng Industrial Co., Ltd.	SS-120						
			Inalways Corporation	0711 series	1					
			Zhejiang LECI	DB-8						
			Electronics Co., Ltd.		4					
			Rich Bay Co., Ltd. Sun Fair Electric Wire &	R-201SN90						
			Cable (HK)Co. Ltd.	S-01						
			TECX-UNIONS	CO 222 corios	0.54.050\/					
			Technology Corporation	SO-222 series	Standard sheet: C8					
			Rong Feng Industrial Co., Ltd.	RF-180	otandard sheet. Oo					
			Inalways Corporation	0721 series						
			Kunshan Dlk Electronics Technology Co., Ltd	CDJ-8						
			WOER	RSFR						
			HEAT-SHRINKABLE	RSFR-H	600V, 125°C					
			MATERIAL CO LTD	RSFR-HPF						
			QIFURUI ELECTRONICS CO	QFR-h	600V, 125°C					
				SALIPT S-901-		1				
		Insulating tube used on	DONGGUAN SALIPT CO LTD	300 SALIPT S-901- 600	Min. 300V, 125°C	cURus				
9	9	appliance inlet (Not shown)	GUANGZHOU KAIHENG ENTERPRISE GROUP	K-2 (+) K-2 (CB)	Min. 300V, 125°C					
			CHANGYUAN ELECTRONICS CO LTD	CB-HFT	Min. 300V, 125°C					
			WOLIDA TRADING CO LTD	RSFR-H	600V, 125°C					

4.0	.0 Critical Components									
P	Item		Manufacturer/		Technical data and	Mark(s) of				
Photo #	no. ¹	Name	trademark ²	Type / model ²	securement means	conformity ³				
9	10	Internal primary wiring	DONGGUAN YUE YANG WIRE & CABLE CO LTD YONG HAO ELECTRICAL INDUSTRY CO LTD HIP TAI ELECTRIC WIRE CO KUNSHAN NEW ZHICHENG ELECTRONICS TECHNOLOGIES CO LTD SHENG YU ENTERPRISE CO LTD SUZHOU YEMAO ELECTRONIC CO LTD SUZHOU HONGMENG ELECTRONIC CO LTD ZHUANG SHAN CHUAN ELECTRICAL PRODUCTS (KUNSHAN) CO LTD SUZHOU QCTECH CO		cURus					
13	11	Varistor ⁵ (MOV1) (optional)	LTD Panasonic Corporation Brightking Co., Ltd. EPCOS Thinking Electronic Industrial Co., Ltd. Success Electronics Co., Ltd.	ERZV20D241 (V20241U) 241KD20J S20K150 TVR20241K SVR20D241K	Max continuous voltage: 150VAC	cURus				
14	12	Insulating sheet ⁵	FORMEX,DIV OF IL TOOL WORKS INC, FRMRLY FASTEX, DIV OF IL TOOL WORKS INC MIANYANG LONGHUA FILM CO LTD SKC CO LTD TORAY INDUSTRIES INC SABIC INNOVATIVE PLASTICS US L L C	FORMEX GK series PP-WT-20 SH71S Lumirror H10 FR60 series FR63 series FR65 series FR7 series FR700 series PP-BK series PP-WT series FORMEX-18 FORMEX-17	V-0, min. 0.4 mm thickness, 115°C only for GT-41134-0606-W2-TAB VTM-0, min. 0.4 mm thickness, 65°C VTM-2, min. 0.4 mm thickness, 105°C VTM-2, min. 0.4 mm thickness, 105°C V-0, min. 0.4 mm thickness, 130°C V-0, min. 0.4 mm thickness, 80°C	cURus				

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4.0 Critical Components Item Manufacturer/ Mark(s) of Technical data and Name Type / model² no.1 trademark² securement means conformity³ Min. 24AWG, min. 300Vac, 14 Output cord Various cURus 13 Various min. 80°C NEMA 1-15P 15 14 Plug portion GlobTek Various NR

NOTES:

- 1) Not all item numbers are indicated (called out) in the photos, as their location is obvious.
- 2) "Various" means any type, from any manufacturer that complies with the "Technical data and securement means" and meets the "Mark(s) of conformity" can be used.
- 3) Indicates specific marks to be verified, which assures the agreed level of surveillance for the component. "NR" indicates Unlisted and only visual examination is necessary. "See 5.0" indicates Unlisted components or
- indicates Unlisted and Only visual examination is necessary. See 5.0 Indicates Unlisted components of assemblies to be evaluated periodically refer to section 5.0 for details.
- 4) For GT-41134-0606-W2-TAB, the fuse rating is T6.3A and evaluated separately.
- 5) only for GT-41134-0606-W2-TAB

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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.

- Spacing Refer to illustration No(s) 2a-2b 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.
- 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.
- 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.
- Polarized Connection This product is provided with a polarized power supply connection.
- 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.
- Schematics Refer to Illustration No(s). 3a-3b, 4a-4d for schematics & PCB layout requiring verification during Field Representative Inspection Audits.
- 9. Markings The product is marked as follows: brand name, model number, electrical ratings, manufacturer. Refer to Illustration No. 5 for details.
- 10. Cautionary Markings Refer to illustrations No. 5 for details.
- 11. Safety Instructions Accompanying Documents are provided for some critical issue like technical data, safety warnings, necessary information to set up, but further evaluation is needed on end product level.

7.0 Illustrations

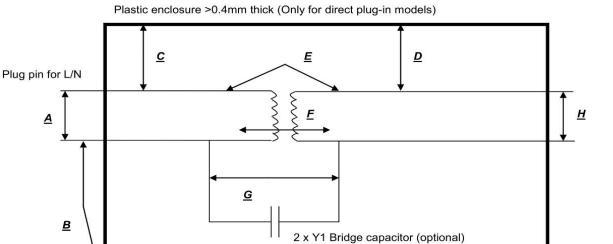
Illustration 1 - Model list

Model list

Model	voltage	Max. current	Max. power
GT*41134**03*** GT*96060**03***	3.3V	1.8A	6W
GT*41134**04*** GT*96060**04***	3.4-4V	1.76A	6W
GT*41134**06*** GT*96060**06***	4.1-6V	1.46A	6W
GT*41134**12*** GT*96060**12***	6.1-12V	0.98A	6W
GT*41134**15*** GT*96060**15***	12.1-15V	0.50A	6W
GT*41134**18*** GT*96060**18***	15.1-18V	0.40A	6W
GT*41134**24*** GT*96060**24***	18.1-24V	0.33A	6W
GT*41134**36*** GT*96060**36***	24.1-36V	0.25A	6W
GT*41134**48*** GT*96060**48***	36.1-48V	0.16A	6W
GT-41134-0606-W2-TAB	6V	1A	6W

7.0 Illustrations

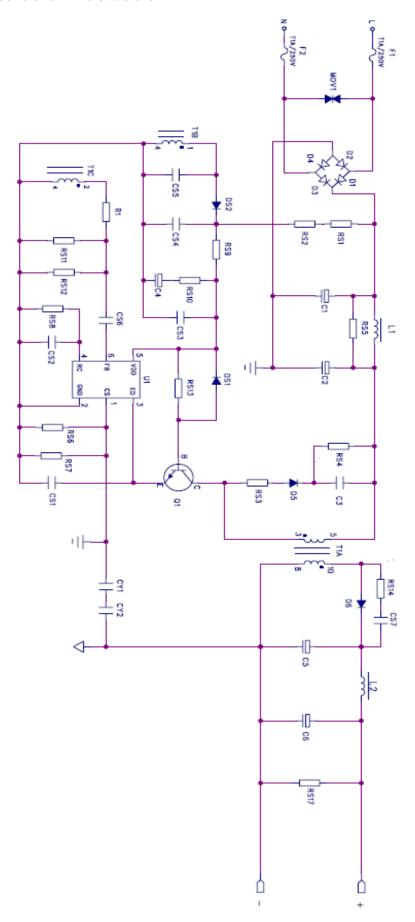
Illustration 2 - Insulation diagram



TABL	.E: Insulation d	iagram (n	neasure	d values)	л				P.s
Pollu	tion degree			: 2.1					- .1
Over	voltage catego	гу		i. II.s					—
Altitu	de				m, use mu ple factor 1			OPP,	
	tional details or oplied parts				one	reas_ for details).1	+	1
Area.	Number and type of Means of Protection:	CTI↓ (IIIb, unless is		gvoltage	creepage	Required clearance (mm).	creepage	Measured clearance (mm).	Remarks.
	MOOP, MOPP	known).	Vrms.1	VRK.	(mm).1	(mm).1	(mm).1	(mm).1	
A.1	MOOP.1	IIIb.ı	240.1	л	2.4.1	3.0.1	3.1**.1	3.1**.1	Mains opposite polarity.
В.,	2MOPP.,	IIIb.s	240.1	а	8.1	6.5.1	10.4.1	10.4.1	Mains (plug pin) to enclosure (accessible position during normal use).
C. ₁	2MOPP.,	IIIb.ı	240.1	л	7.0	7-0	7.1	T-1	Mains to external of enclosure (>0.4mm thick plastic enclosure, solid insulation).
D.1	2MOPP.	IIIb.s	a	Max. 48.	7-1	To 1	7.1	- .1	Secondary to external of enclosure (>0.4mm thick plastic enclosure, solid insulation).1
E.1	2MOPP.1	IIIb.ı	250*.1	л	8.1	6.5.1	8.1.1	8.1.1	Mains to secondary on PCB.1
Fa	2MOPP. ₁	IIIb.ı	250*.1	а	7.0	T/I	Total	7.1	Mains to secondary on transformer, approved TIW used.1
G.1	2MOPP.s	IIIb.s	250*.1	л	8.1	6.5.4	8.2.1	8.2.1	Mains to secondary on bridge capacitors, see 8.5.1.2 and 8.8.3.1
Ha	2MOPP.1	IIIb.s	.1	Max. 48.	7.1	7.1	7.1	7.1	Accessible part per 8.4.2c).

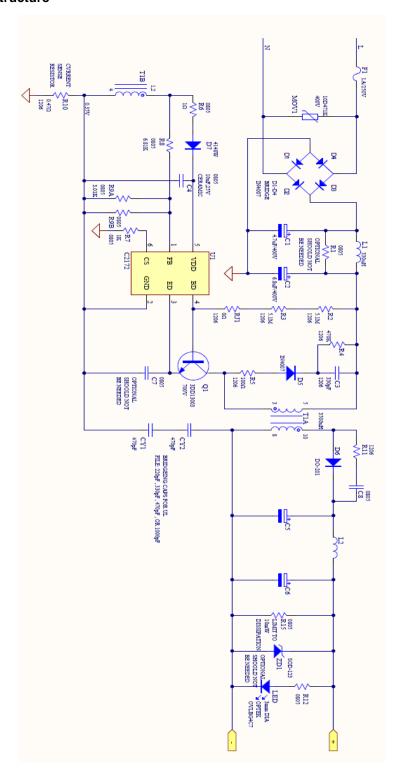
7.0 Illustrations

Illustration 3a - CIRCUIT DIAGRAM First, Second and Third structure



7.0 Illustrations

Illustration 3b - CIRCUIT DIAGRAM Fourth structure

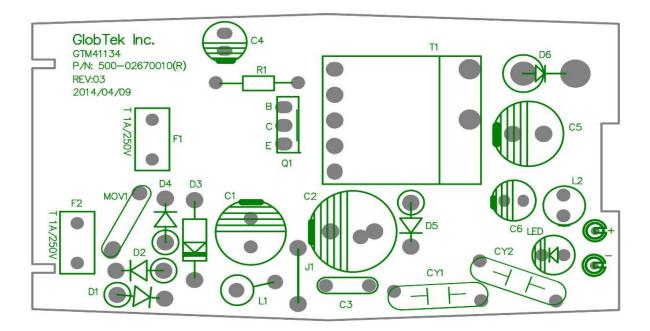


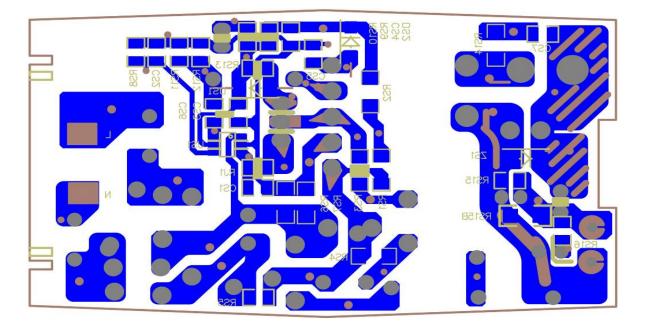
Report No. 151100934SHA-001 GlobTek, Inc.

Issued: 25-Dec-2015 Revised: None

7.0 Illustrations

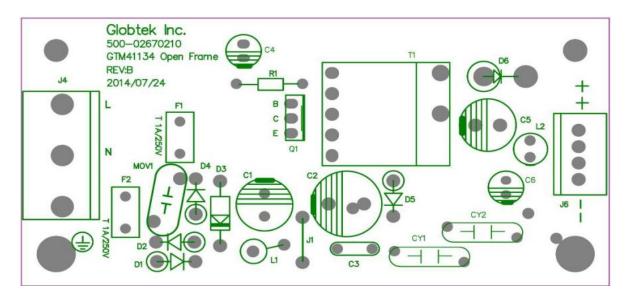
Illustration 4a - PCB LAYOUT FOR ADAPTER MODEL GT*41134******(FIRST STRUCTURE)

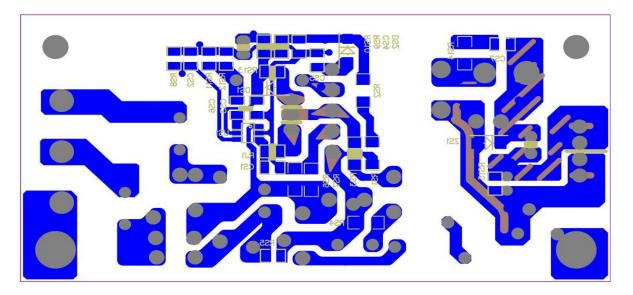




7.0 Illustrations

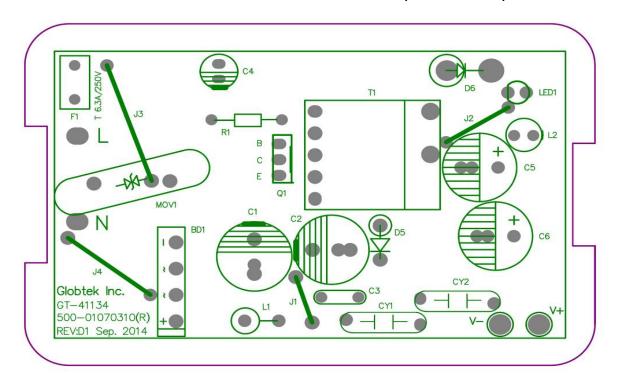
Illustration 4b - PCB LAYOUT FOR OPEN FRAME MODEL(Second structure)

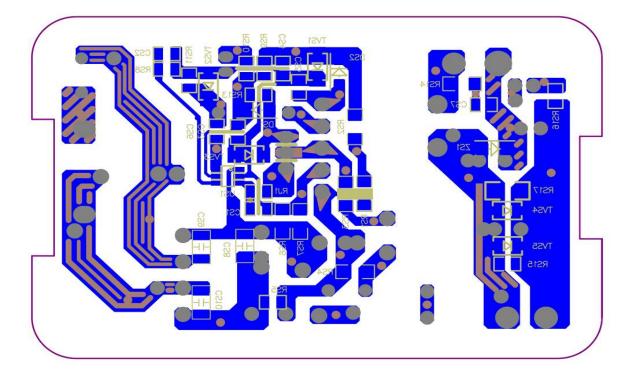




7.0 Illustrations

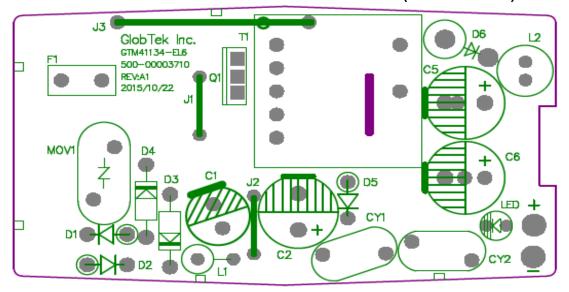
Illustration 4c - PCB LAYOUT for model GT-41134-0606-W2-TAB (Third structure)

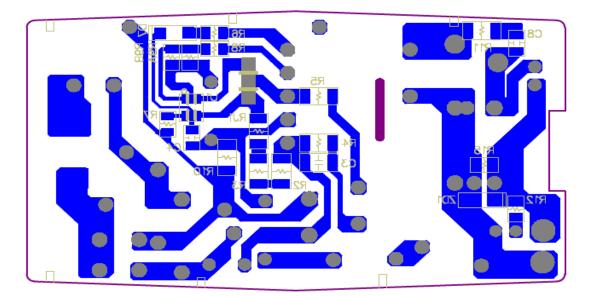




7.0 Illustrations

Illustration 4d - PCB LAYOUT for model FOR GT*96060****** MODEL (Fourth structure)





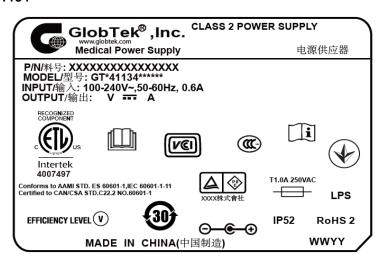
Report No. 151100934SHA-001 GlobTek, Inc.

7.0 Illustrations

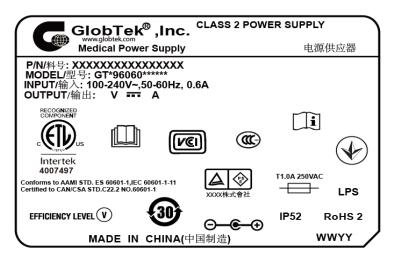
Illustration 5 - Marking

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

GT*41134*****



GT*96060*****



GT-41134-0606-W2-TAB



Issued: 25-Dec-2015

8.0 Test Summary 2015-12-01~2015-12-25 Project No. 151100934SHA **Evaluation Period** Condition Prototype Sample Rec. Date 25-Dec-2015 Sample ID. 015021-56-006 Building No.86, 1198 Qinzhou Road (North), Shanghai 200233, China Test Location Testing Lab Test Procedure 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: AAMI ES60601-1 Issued: 2012/08/20 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance, Amendment 1 CAN/CSA-C22.2 No.60601-1:14, Third Edition Issued: 2014/03/01 - Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance 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 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 Mold Stress Relief 15.3.6 Transformer Short-Circuit 15.5.1.2 Transformer Overload 15.5.1.3

Test Description	IEC 60601-1-11 Issued: 2015/01/20 Ed. 2 Medical Elec. Equip Part 1-11: Gen. Req. for Basic Safety & Essential Perf Collateral Standard - Req. for Medical Elec. Equip. & Medical Elec. Systems Used in the Home Healthcare Environment Clause
Environmental condition test of transport and storage between uses	4.2.2
Continuous operating conditions	4.2.3.1
Shock test	10.1.2 a)
Vibration test	10.1.2 b)

8.1 Signatures

Transformer Dielectric Strength

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:	Skot Shi	Reviewed by:	Justin Yu
Title:	Project engineer	Title:	Reviewer
Signature:	Skot Shi	Signature:	Jan L

15.5.2

Issued: 25-Dec-2015

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. GlobTek, Inc. **BASIC LISTEE** 186 Veterans Dr. Northvale, NJ 07647 USA Address 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**

Issued: 25-Dec-2015

10.0 General Information

The Applicant and Manufacturer have agreed to produce, test and label ETL Listed products in accordance with the requirements of this Report. The Manufacturer has also agreed to notify Intertek and to request authorization prior to using alternate parts, components or materials.

COMPONENTS

Components used shall be those itemized in this Intertek report covering the product, including any amendments

LISTING MARK

The ETL Listing mark applied to the products shall either be separable in form, such as labels purchased from Intertek, or on a product nameplate or other media only as specifically authorized by Intertek. Use of the mark is subject to the control of Intertek.

The mark must include the following four items:

- 1) applicable country identifiers "US" and/or "C" or "US", "C" and "EU"
- 2) the word "Listed" or "Classified" or "Recognized Component" (whichever is appropriate)
- 3) a control number issued by Intertek
- 4) a product descriptor that identifies the standards used for certification. Example:

For US standards, the words, "Conforms to" shall appear with the standard number along with the word, "Standard" or "Std." Example: "Conforms to ANSI/UL Std. XX."

For Canadian standards, the words "Certified to CAN/CSA Standard CXX No. XX." shall be used, or abbreviated, "Cert. to CAN/CSA Std. CXX No. XX."

Can be used together when both standards are used.

Note: A facsimile must be submitted to Intertek, Attn: Follow-up Services for approval prior to use. The facsimile need not have a control number. A control number will be issued after signed Certification Agreements have been received by the Follow-up Services office, approval of the facsimile of your proposed Listing Mark, satisfactory completion of the Listing Report, and scheduling of a factory

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.
- 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.

Issued: 25-Dec-2015 GlobTek, Inc. Revised: None

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.

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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:					
Product	Test Voltage	Test Time			
Between L/N and secondary output	4000Vac	60 s			

12.0 Revision SummaryThe following changes are in compliance with the declaration of Section 8.1: Project Handler/ Section Item Description of Change Proj # Site ID Reviewer None

Issued: 25-Dec-2015