

RECOGNIZED COMPONENT **Constructional Data Report (CDR)**

1.0 Reference and Address			
Report Number	140900039SHA-001	Original Issued:	21-Oct-2014
		Revised:	None
Standard(s)	ANSI/AAMI ES60601-1:2005/A1:2012 Issued: 2012/08/20 Medical electrical equipment – Part 1: General Requirements for Basic Safety and Essential Performance, Amendment 1; CAN/CSA-C22.2 No. 60601-1:14, Third Edition Issued: 2014/03/01 - Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance.		
Applicant	GlobTek, Inc.	Manufacturer	GlobTek (Suzhou) Co., Ltd.
Address	186 Veterans Dr. Northvale, NJ 07647 USA	Address	Building 4. No 76 JinLing East Road, Suzhou Industrial Park, Suzhou, JiangSu, 215021
Country	USA	Country	China
Contact	Hans Moritz	Contact	Demon Zhou
Phone	(201)784-1000 Ext.253	Phone	86 512 6279 0301 Ext.189
FAX	(201)784-0111	FAX	86 512 6279 0355
Email	Moritzh@globtek.com	Email	demon.zhou@globtek.cn

2.0 Product Description	
Product	ITE/Medical Power Supply
Brand name	GlobTek
Description	<p>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 three structure types respectively. One 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.</p> <p>The other one 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.</p> <p>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.</p> <p>All the models except GT-41134-0606-W2-TAB were evaluated for maximum manufacturer's recommended ambient of 40 °C.</p> <p>Model GT-41134-0606-W2-TAB was evaluated for maximum manufacturer's recommended ambient of 50 °C.</p> <p>All the types are designed for continuous operation and no applied part is defined.</p> <p>The insulation construction of EUT is evaluated as 2MOPP in this report as customer's request.</p>
Models	<p>GT*41134-***-*** (The 1st "*" part can be "M" or '-' or 'H'; The 2nd "*" part can be "01" to "06", with interval of 1; The 3rd "*" part can be "03", "04", "06", "12", "15", "18", "24", "36" or "48"; The 4th "*" part can be "-0.1" to "-11.9" with interval of 0.1 or blank; The 5th "*" part can be 'F', "FW" or blank; The 6th "*" part can be 'T' or blank. The 7th "*" part can be '2', '3', '3A' or blank.) or GT-41134-0606-W2-TAB</p>
Model Similarity	<p>GT*41134-***-***</p> <p>The 1st "*" part can be 'M' or '-' or 'H' for market identification and not related to safety.</p> <p>The 2nd "*" denotes the rated output wattage designation, which can be "01" to "06", with interval of 1.</p> <p>The 3rd "*" denotes the standard rated output voltage designation, which can be "03", "04", "06", "12", "15", "18", "24", "36" or "48". These standard rated output voltage designations correspond to seven isolated transformer models (See the section 4.0 for details). Each transformer model is identical in insulation construction including clearance and creepage except number of turns per coil.</p> <p>The 4th "*" 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.</p> <p>The 3rd "*" and 4th "*" together denote the output voltage, with a range of 3.3 - 48 volts.</p> <p>The 5th "*" can be 'F' or "FW" to denote open frame model with connector which is fixing on the PCB.</p> <p>'F' represent models with Class I connector and "FW" represent models with Class II connector</p> <p>The 6th "*" can be blank or 'T'.</p> <p>When the 6th "*" is 'T' to denote open frame model with appliance inlet.</p> <p>When the 6th "*" is 'T', the 7th "*" can be '2' representing models with Class II inlet or '3' and "3A" representing model with two types of Class I inlets C14 & C6.</p> <p>The last three asterisks with hyphen "-***" are blank to denote direct plug-in model series.</p>
Ratings	<p>Input: 100-240V~, 50-60Hz, 0.6A for GT*41134-***-***;</p> <p>120V~, 60Hz, 0.3A for GT-41134-0606-W2-TAB</p> <p>Output: Refer to illustration No.1 for details.</p>
Other Ratings	N/A

2.0 Product Description

Conditions of Acceptability	<p>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.</p> <p>1. Scope of Power Supply evaluation defers the following clauses to be determined as part of the end product investigation:</p> <ul style="list-style-type: none">• 60601-1 Clause 7.5 (Safety Signs),• 60601-1 Clause 7.9 (Accompanying Documents are provided for some critical issue like technical data, safety warnings, necessary information to set up, but further evaluation is needed on end product level.),• 60601-1 Clause 8.11.5 (Mains Fuse with High Breaking Capacity),• 60601-1 Clause 9 (ME Hazard), except 9.1 and 9.3 are evaluated,• 60601-1 Clause 10 (Radiation),• 60601-1 Clause 11.7 (Biocompatibility),• 60601-1 Clause 14 (PEMS),• 60601-1 Clause 15 (Construction),• 60601-1 Clause 16 (ME Systems),• 60601-1 Clause 17 (EMC) <p>2. For open frame model</p> <ul style="list-style-type: none">• Suitability of the enclosure should be evaluated when installed in the end product including access to energized parts, clearance & creepage distance measurement and mechanical strength.• Temperature Testing should be performed on this component when installed in the end product.
-----------------------------	--

3.0 Product Photographs

PHOTO 1 - EXTERNAL VIEW – 1 OF ADAPTER MODEL GT*41134-***



PHOTO 2: EXTERNAL VIEW – 2 OF ADAPTER MODEL GT*41134-***



3.0 Product Photographs

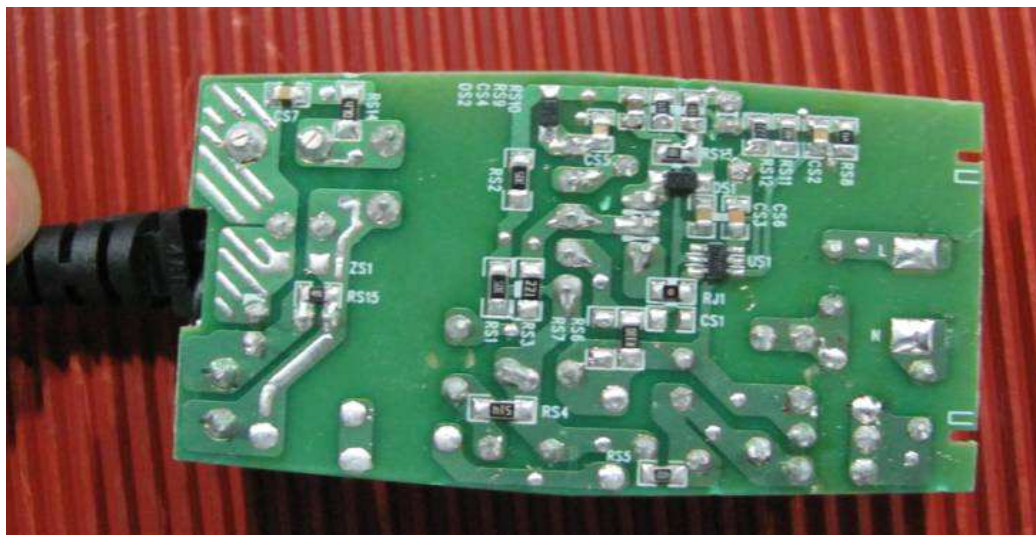
PHOTO 3: EXTERNAL VIEW – 3 OF ADAPTER MODEL GT*41134-***



PHOTO 4: INTERNAL VIEW – 4 OF ADAPTER MODEL GT*41134-***



PHOTO 5: COMPONENT SIDE VIEW OF PCB OF ADAPTER MODEL GT*41134-***



3.0 Product Photographs

PHOTO 7: COMPONENT SIDE VIEW OF OPEN FRAME MODEL

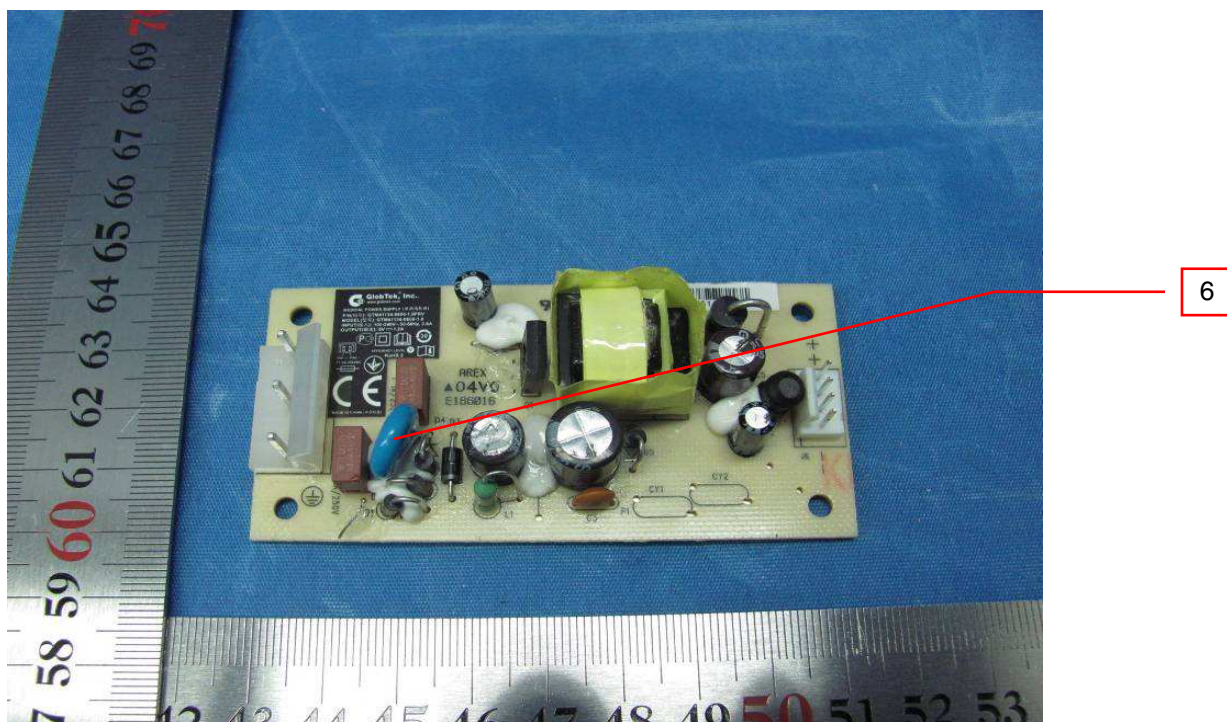
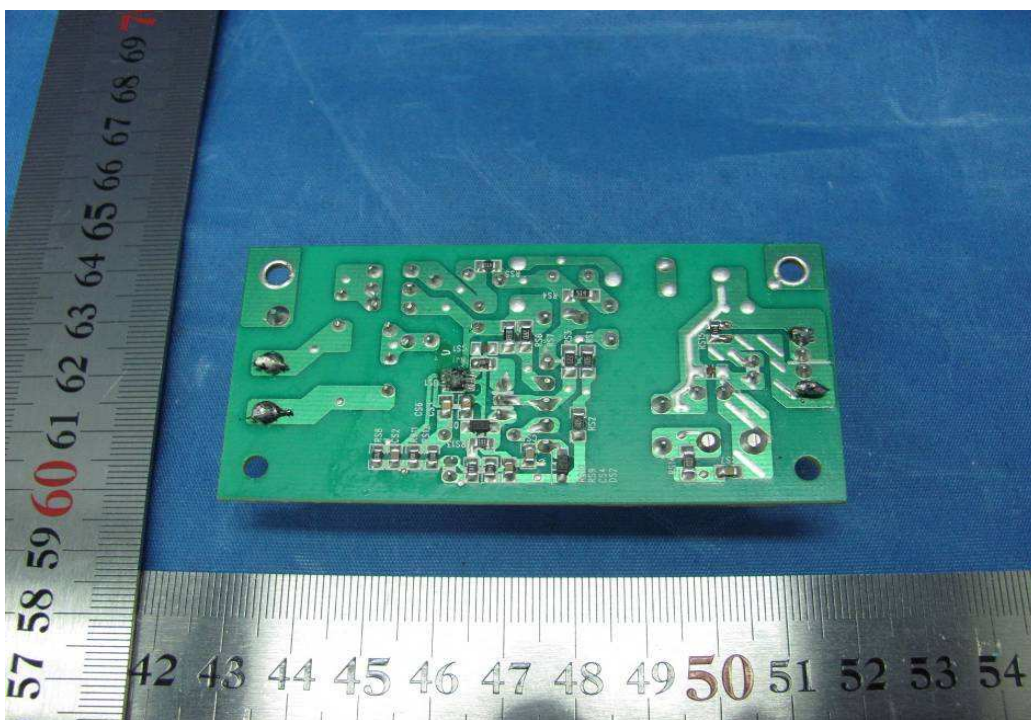


PHOTO 8: SOLDERING SIDE VIEW OF OPEN FRAME MODEL



3.0 Product Photographs

PHOTO 9: COMPONENT SIDE OF OPEN FRAME MODEL WITH APPLIANCE INLET

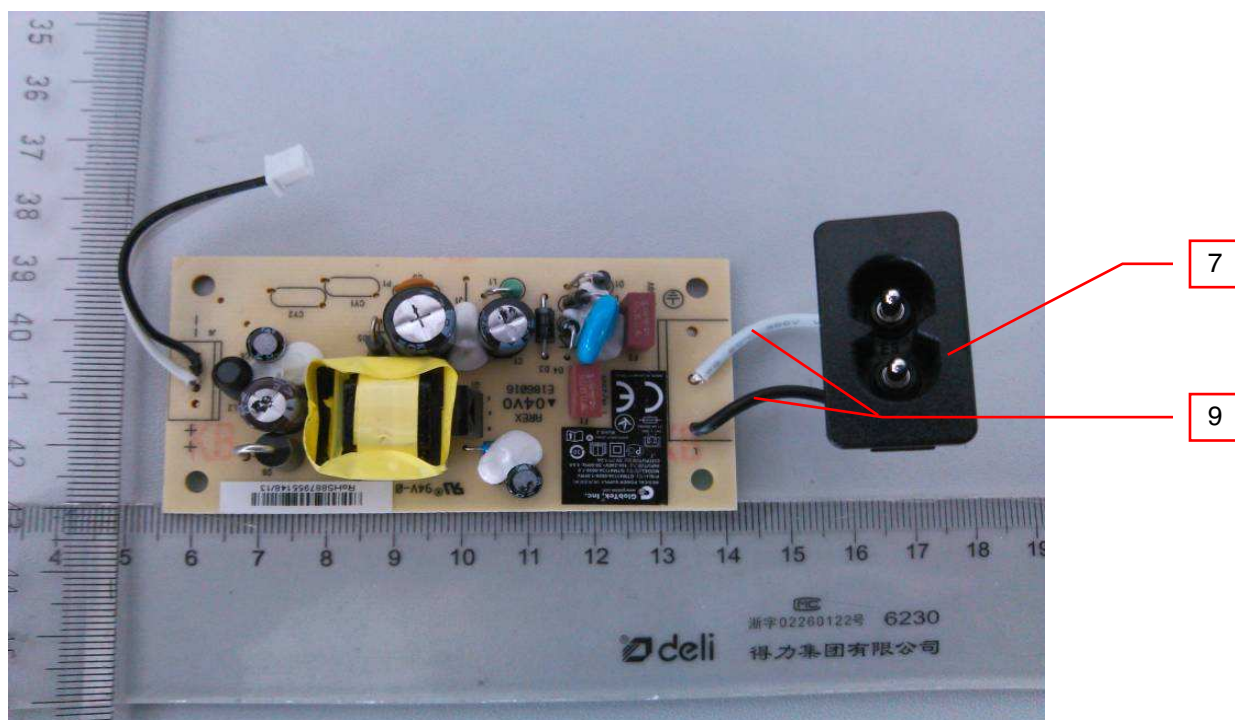
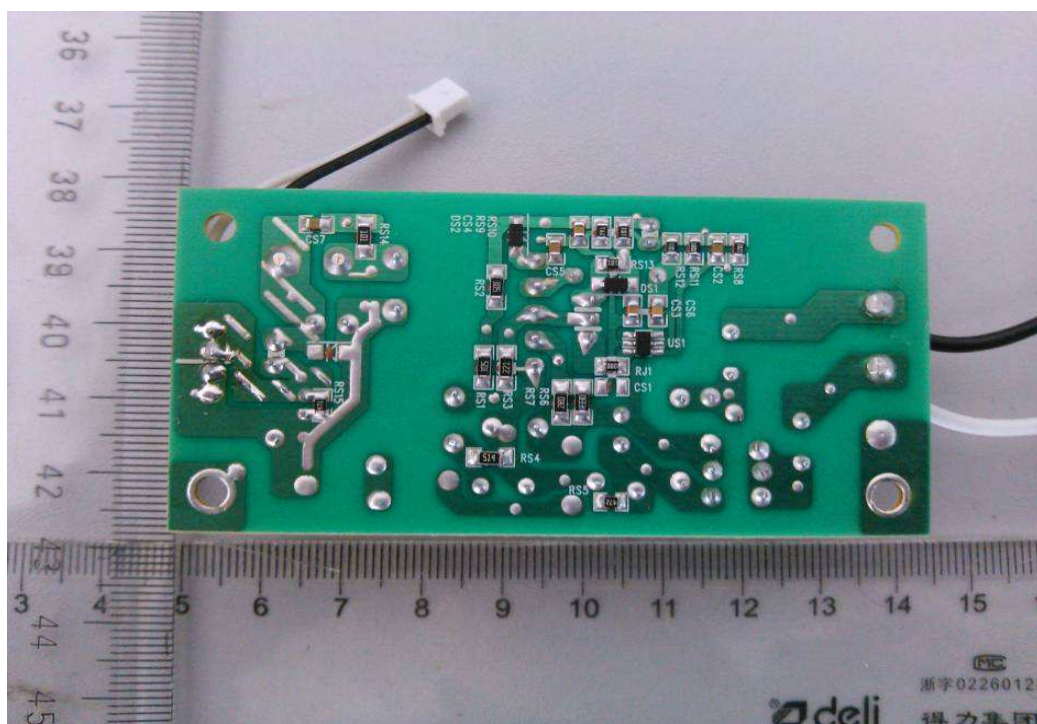


PHOTO 10: SOLDERING SIDE OF OPEN FRAME MODEL WITH APPLIANCE INLET



3.0 Product Photographs

PHOTO 11: EXTERNAL VIEW - 1 OF MODEL GT-41134-0606-W2-TAB



PHOTO 12: EXTERNAL VIEW - 2 OF MODEL GT-41134-0606-W2-TAB



3.0 Product Photographs

Photo 13: Component side view of PCB of model GT-41134-0606-W2-TAB

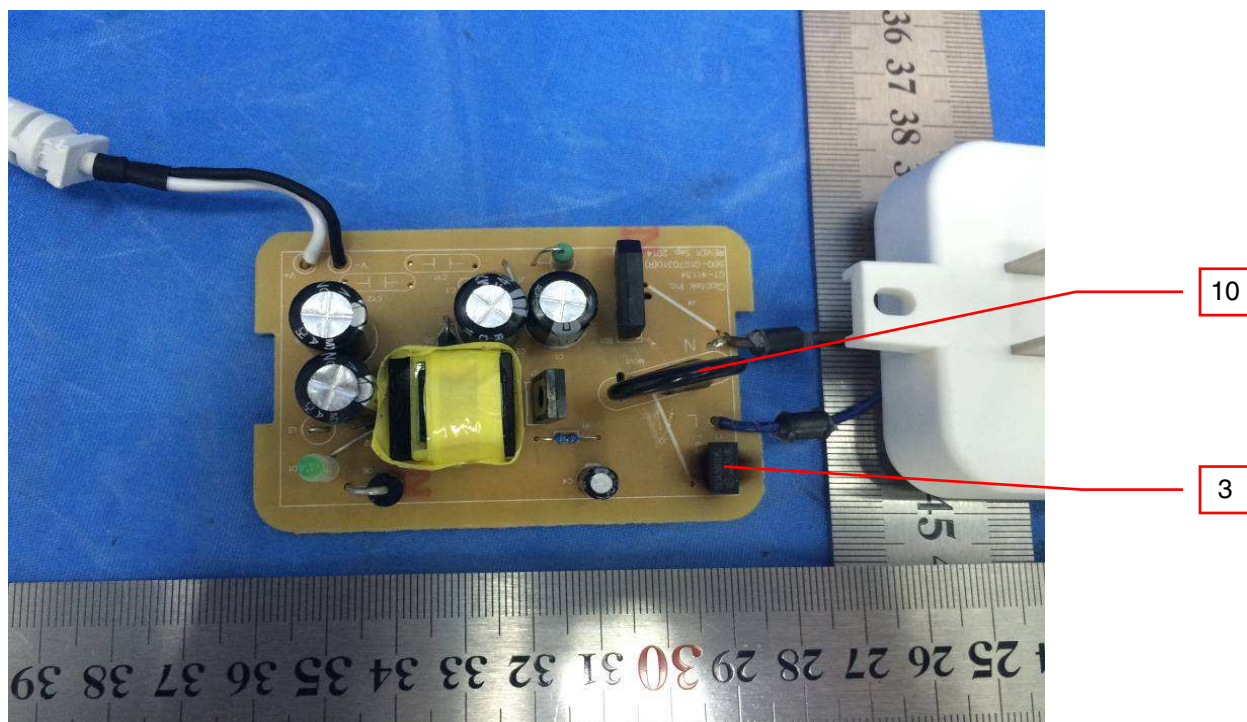
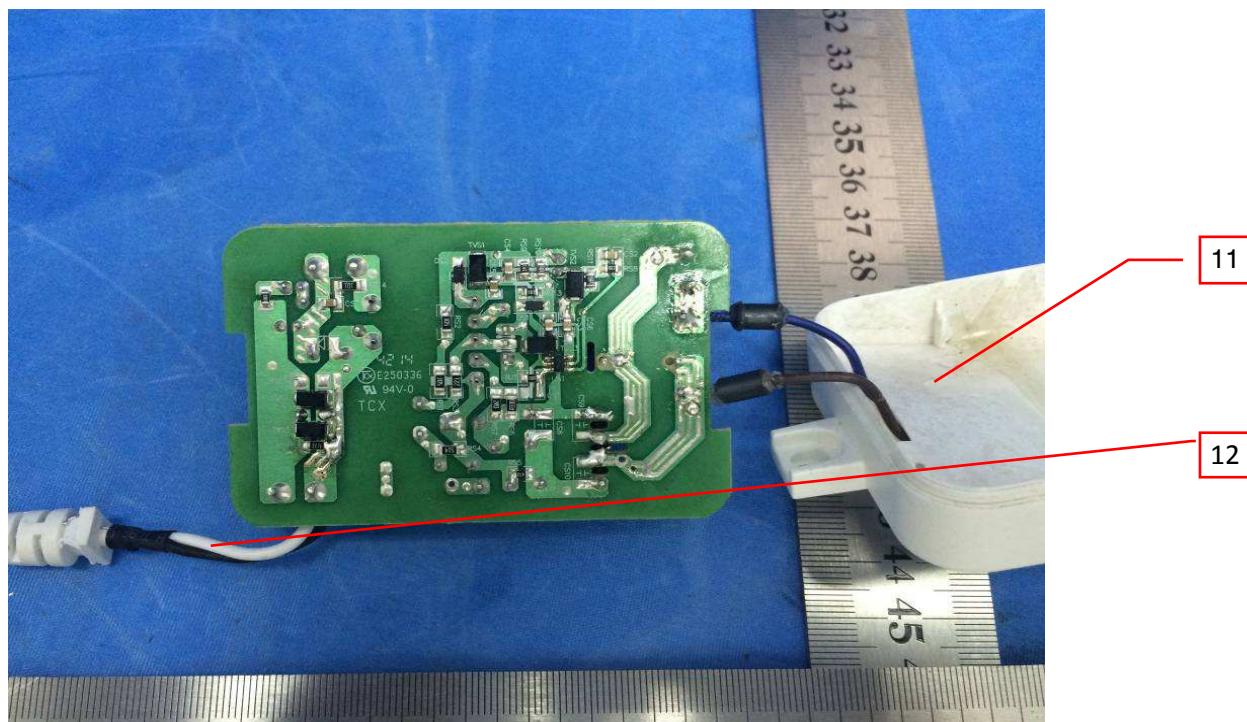


Photo 14: Soldering side view of PCB of model GT-41134-0606-W2-TAB



3.0 Product Photographs

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

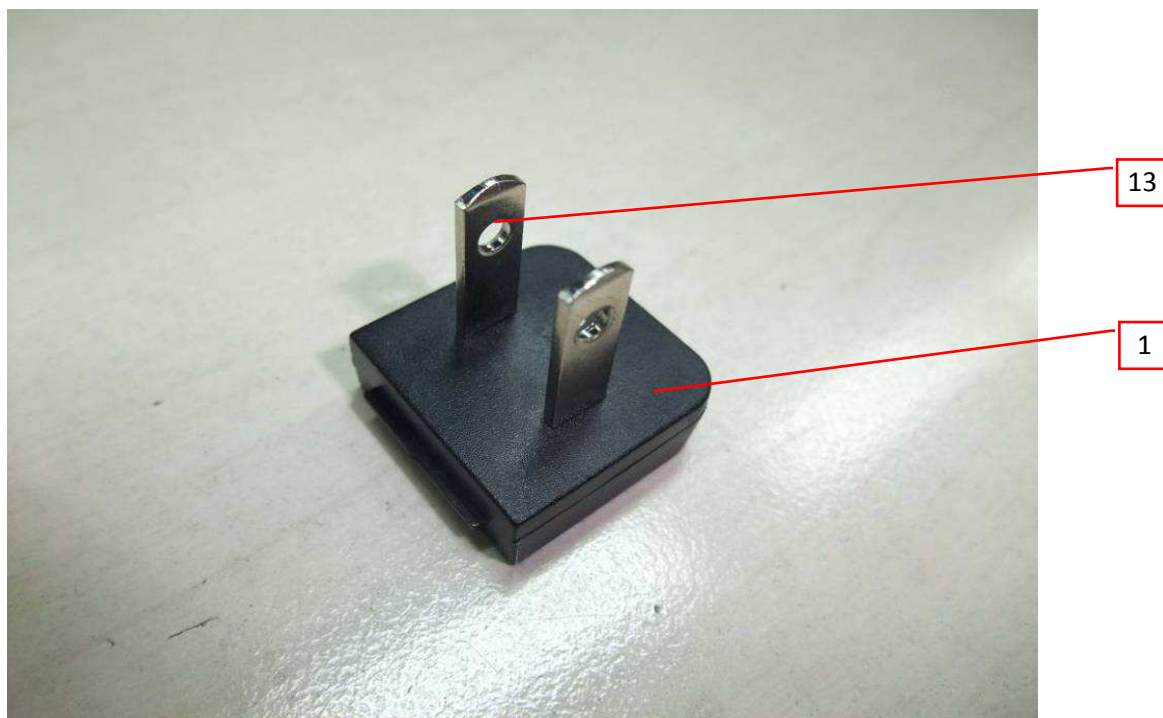


Photo 16: Connector side view of NEMA 1-15P plug portion



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		1	Enclosure & Blade holder	SABIC INNOVATIVE PLASTICS B V	SE1 SE1X	Min. V-1 at 1.5 mm thickness	cURus
				SABIC INNOVATIVE PLASTICS B V	SE100	Min. V-1 at 2.0 mm thickness	
				SABIC INNOVATIVE PLASTICS B V	C2950 CX721 EXCY0098 940	Min. V-0 at 2.0 mm thickness	
				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	
5		2	PCB material	TECHNI TECHNOLOGY LTD	T2A T2B T4	Min. 1.6 mm thickness, min. V- 0, 130°C	cURus
				DONGGUAN HE TONG ELECTRONICS CO LTD	CEM1 2V0 FR4		
				CHEERFUL ELECTRONIC	03 03A		
				DONGGUAN DAYSUN ELECTRONIC CO LTD	DS2		
				SUZHOU CITY YILIHUA ELECTRONICS CO LTD	YLH-1		
				SHANGHAI AREX PRECISION ELECTRONIC CO LTD	04V0 02V0		
				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		
				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, 13		3	Fuse ⁴ (F1, F2) (F2 is optional)	CONQUER ELECTRONICS CO LTD	MST	T1A or T6.3A, 250V, Rated breaking capacity 100A	cURus
				EVER ISLAND ELECTRIC CO LTD &	2010	T1A or T6.3A, 250V, Rated breaking capacity 130A	
				BEL FUSE INC	RST	T1A or T6.3A, 250V, Rated breaking capacity 100A	
					5ST	T1A or T6.3A, 250V, Rated breaking capacity 35A	
				COOPER BUSSMANN LLC	SS-5	T1A or T6.3A, 250V, Rated breaking capacity 35A	
				DAS & SONS INTERNATIONAL LTD	385T series	T1A or T6.3A, 250V, Rated breaking capacity 35A	
				SHENZHEN LANSO ELECTRONICS CO LTD	SMT	T1A or T6.3A, 250V, Rated breaking capacity 35A	
				WALTER ELECTRONIC CO LTD	ICP series	T1A or T6.3A, 250V, Rated breaking capacity 50A.	
				ZHONG SHAN LANBAO ELECTRICAL APPLIANCES CO LTD	RTI-10 series	T1A or T6.3A, 250V, Rated breaking capacity 50A	
				SUN ELECTRIC CO	5T	T1A or T6.3A, 250V, Rated breaking capacity 100A	
5		4	Isolation transformer (T1)	GlobTek/ BOAM/ HAOPUWEI	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 XF00814 for 24.1-36V XF00841 for 36.1-48V	Class B with insulation system below.	NR
5	4a	Insulation system		ENG130-1	Class B	cURus	
			GLOBTEK INC	GTX-130-TM			
			SHAN DONG BOAM ELECTRIC CO LTD	BOAM-01			
			WUXI HAOPUWEI ELECTRONICS CO LTD	ZT-130			

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		5	Y-Capacitor (CY1 & CY2) (Optional) (Not shown)	TDK CORP	CD	Type Y1, max. 470pF, min. 250V, min. 125°C	cURus
				SUCCESS ELECTRONICS CO LTD	SE SB	Type Y1, max. 470pF, min. 250V, min. 125°C	
				MURATA MFG CO LTD	KX	Type Y1, max. 470pF, min. 250V, min. 125°C	
				WALSIN TECHNOLOGY CORP	AH	Type Y1, max. 470pF, min. 250V, min. 125°C	
				JYA-NAY CO LTD	JN	Type Y1, max. 470pF, min. 250V, min. 125°C	
				HAOHUA ELECTRONIC CO	CT7	Type Y1, max. 470pF, min. 250V, min. 125°C	
				JERRO ELECTRONICS CORP	JX-series	Type Y1, max. 470pF, min. 250V, min. 125°C	
				JYH CHUNG ELECTRONICS CO LTD	JD	Type Y1, max. 470pF, min. 250V, min. 125°C	
				WELSON INDUSTRIAL CO LTD	WD	Type Y1, max. 470pF, min. 250V, min. 125°C	
7		6	Varistor (MOV1) (Optional)	JOYIN CO LTD	07N471K 10N471K 14N471K	Maximum continuous voltage: 300Vac	cURus
				CENTRA SCIENCE CORP	07D471K 10D471K 14D471K		
				THINKING ELECTRONIC INDUSTRIAL CO LTD	TVR07471K TVR10471K TVR14471K		
				SUCCESS ELECTRONICS CO LTD	SVR07D471K SVR10D471K SVR14D471K		
				CERAMATE TECHNICAL CO LTD	GNR07D471K GNR10D471K GND14D471K		
				BRIGHTKING (SHENZHEN) CO LTD	07D471K 10D471K 14D471K		
				LIEN SHUN ELECTRONICS CO LTD	07D471K 10D471K 14D471K		
				HONGZHI ENTERPRISES LTD	HEL-07D471K HEL-10D471K HEL-14D471K		
				GUANGXI NEW FUTURE INFORMATION INDUSTRY CO LTD	07D471K 10D471K 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
9		7	AC inlet (Class I or Class II)	Zhejiang LECI Electronics Co., Ltd.	DB-6	2.5A, 250Vac Standard sheet: C6	cURus
				Rich Bay Co., Ltd.	R-30790 R-307		
				Sun Fair Electric Wire & Cable (HK)Co. Ltd.	S-02		
				TECX-UNIONS Technology Corporation	TU-333		
				Rong Feng Industrial Co., Ltd.	RF-190		
				Inalways Corporation	724		
				Kunshan Dlk Electronics Technology Co., Ltd	CDJ-2		
				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 series		
				Zhejiang LECI Electronics Co., Ltd.	DB-8		
				Rich Bay Co., Ltd.	R-201SN90		
				Sun Fair Electric Wire & Cable (HK)Co. Ltd.	S-01		
				TECX-UNIONS Technology Corporation	SO-222 series		
				Rong Feng Industrial Co., Ltd.	RF-180		
				Inalways Corporation	0721 series		
				Kunshan Dlk Electronics Technology Co., Ltd	CDJ-8		
9		8	Insulating tube used on appliance inlet (Not shown)	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	
				GUANGZHOU KAIHENG ENTERPRISE GROUP	K-2 (+) K-2 (CB)	Min. 300V, 125°C	
				CHANGYUAN ELECTRONICS (SHENZHEN) CO LTD	CB-HFT	Min. 300V, 125°C	
				SHENZHEN WOLIDA TRADING CO LTD	RSFR-H	600V, 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
9		9	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 LTD	1007, 1015, 1185, 2464, 2468	Min. 18AWG, min. 300Vac, min. 80℃	cURus
13		10	Varistor (MOV1) (optional) (only for GT-41134- 0606-W2-TAB)	Panasonic Corporation Brightking (Shenzhen) Co., Ltd. EPCOS Thinking Electronic Industrial Co., Ltd. Success Electronics Co., Ltd.	ERZV20D241 (V20241U) 241KD20J S20K150 TVR20241K SVR20D241K	Max continuous voltage: 150VAC	cURus
14		11	Insulating sheet only for GT- 41134-0606- W2-TAB	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 MIANYANG LONGHUA FILM CO LTD ITW ELECTRONICS COMPONENTS/ PRODUCTS (SHANGHAI) CO LTD	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℃ VTM-0, min. 0.4 mm thickness, 65℃ VTM-2, min. 0.4 mm thickness, 105℃ VTM-2, min. 0.4 mm thickness, 105℃ V-0, min. 0.4 mm thickness, 130℃ V-0, min. 0.4 mm thickness, 80 ℃ V-0, min. 0.4 mm thickness, 100℃	cURus

4.0 Critical Components							
#	Photo	Item no. ¹	Name	Manufacturer/ trademark ²	Type / model ²	Technical data and securement means	Mark(s) of conformity ³
14		12	Output cord	Various	Various	Min. 24AWG, min. 300Vac, min. 80°C	cURus
15		13	Plug portion	GlobTek	Various	NEMA 1-15P	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 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.							

5.0 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.

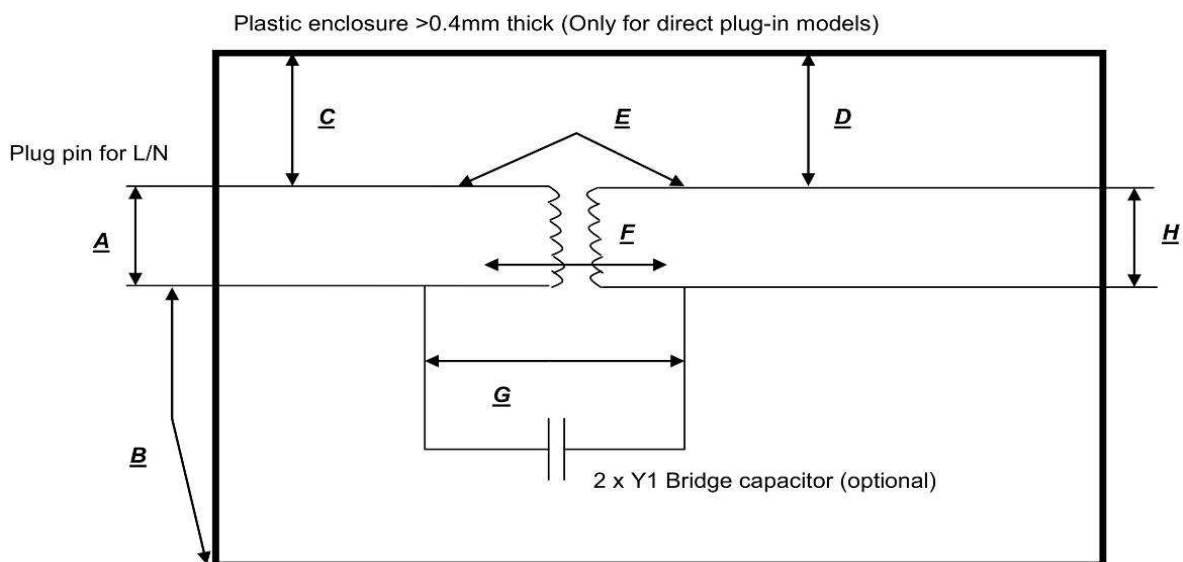
1. Spacing - Refer to illustration No(s) 2a-2b for details.
2. Mechanical Assembly - Components such as switches, fuseholders, connectors, wiring terminals and display lamps are mounted and prevented from shifting or rotating by the use of lockwashers, starwashers, or other mounting format that prevents turning of the component.
3. Corrosion Protection - All ferrous metal parts are protected against corrosion by painting, plating or the equivalent.
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). 3, 4a-4c 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	voltage	Max.current	Max.power
GT*41134-*03-***	3.3V	1.8A	6W
GT*41134-*04*-***	3.4-4V	1.76A	6W
GT*41134-*06*-***	4.1-6V	1.46A	6W
GT*41134-*12*-***	6.1-12V	0.98A	6W
GT*41134-*15*-***	12.1-15V	0.50A	6W
GT*41134-*18*-***	15.1-18V	0.40A	6W
GT*41134-*24*-***	18.1-24V	0.33A	6W
GT*41134-*36*-***	24.1-36V	0.25A	6W
GT*41134-*48*-***	36.1-48V	0.16A	6W

Illustration 2a - Insulation diagram



7.0 Illustrations

Illustration 2b - TABLE: Insulation diagram (measured values)

TABLE: Insulation diagram (measured values)									P
Pollution degree				2					—
Overvoltage category				II					—
Altitude				3000m, use multiple factor 1 for MOPP					—
Additional details on parts considered as applied parts				<input checked="" type="checkbox"/> None <input type="checkbox"/> Areas _____ (See Clause 4.6 for details)					—
Area	Number and type of Means of Protection: MOOP, MOPP	CTI (IIIb, unless is known)	Working voltage		Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
			Vrms	Vpk					
A	MOOP	IIIb	240		2.4	2.3	Min.3.0**	Min,3.0**	Mains opposite polarity
B	2MOPP	IIIb	240		8	5	10.4	10.4	Mains (plug pin) to enclosure (accessible position during normal use)
C	2MOPP	IIIb	240		-	-	-	-	Mains to external of enclosure (>0.4mm thick plastic enclosure, solid insulation)
D	2MOPP	IIIb		Max. 48	-	-	-	-	Secondary to external of enclosure (>0.4mm thick plastic enclosure, solid insulation)
E	2MOPP	IIIb	250*		8	5	8.6	8.6	Mains to secondary on PCB
F	2MOPP	IIIb	250*		-	-	-	-	Mains to secondary on transformer, approved TIW used
G	2MOPP	IIIb	250*		4.0 + 4.0	2.5 + 2.5	>4.0 + >4.0	>4.0 + >4.0	Mains to secondary on bridge capacitors, see 8.5.1.2 and 8.8.3
H	2MOPP	IIIb		Max. 48	-	-	-	-	Accessible part per 8.4.2c)

7.0 Illustrations

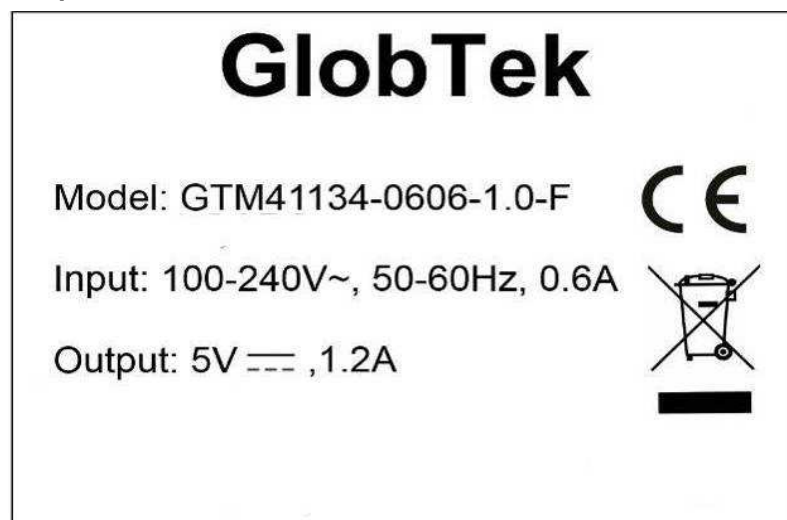
Illustration 5 - Marking

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

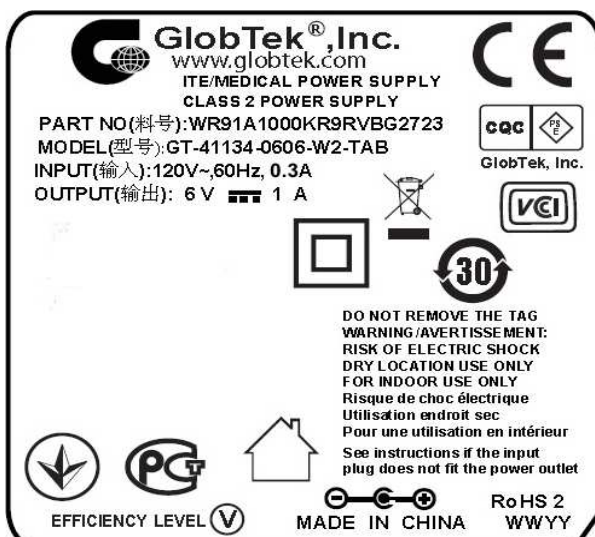
For adapter model



For open frame model



Especially for North American model GT-41134-0606-W2-TAB



ETL Mark
RECOGNIZED
COMPONENT



Conforms to ANSI/AAMI STD
ES60601-1
Certified to CAN/CSA STD C22.2
No.60601-1

8.0 Test Summary

Evaluation Period	2014-09-01 ~ 2014-10-13	Project No.	140900039SHA
Sample Rec. Date	28-Aug-2014	Condition	Prototype
Sample ID	0140828-52-001		
Test Location	Building No.86, 1198 Qinzhou Road (North), Shanghai 200233, China		
Test Procedure	Testing Lab		



Determination of the result includes consideration of measurement uncertainty from the test equipment and methods. The product was tested as indicated below with results in conformance to the relevant test criteria.

The following tests were performed:

Test Description	ANSI/AAMI ES60601-1:2005/A1:2012 Issued: 2012/08/20 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance, Amendment 1; CAN/CSA-C22.2 No. 60601-1:14, Third Edition Issued: 2014/03/01 - Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance. Clause
Power Input	4.11
Humidity Preconditioning	5.7
Accessible Parts	5.9.2
Legibility of Markings	7.1.2
Durability of Markings	7.1.3
Plug Voltage and/or Energy	8.4.3
Working Voltage Measurement	8.5.4
Leakage Current Test terminations	8.7.4
Dielectric Strength Means	8.8.3
Ball Pressure Test	8.8.4.1
Creepage & Clearance Measurements	8.9.4
Excessive Temperature	11.1
Single Fault Conditions	13.2
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
Transformer Dielectric Strength	15.5.2

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:	Jamie Wu	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	ITE/Medical Power Supply

MULTIPLE LISTEE 1	None
Address	
Country	
Brand Name	
ASSOCIATED MANUFACTURER	
Address	
Country	
MULTIPLE LISTEE 1 MODELS	BASIC LISTEE MODELS

MULTIPLE LISTEE 2	None
Address	
Country	
Brand Name	
ASSOCIATED MANUFACTURER	
Address	
Country	
MULTIPLE LISTEE 2 MODELS	BASIC LISTEE MODELS

MULTIPLE LISTEE 3	None
Address	
Country	
Brand Name	
ASSOCIATED MANUFACTURER	
Address	
Country	
MULTIPLE LISTEE 3 MODELS	BASIC LISTEE MODELS

10.0 General Information

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

COMPONENTS

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

LISTING MARK

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

The mark must include the following four items:

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

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

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

Can be used together when both standards are used.

Note: A facsimile must be submitted to Intertek, Attn: Follow-up Services for approval prior to use.

The facsimile need not have a control number. A control number will be issued **after signed Certification Agreements** have been received by the Follow-up Services office, approval of the facsimile of your proposed Listing Mark, satisfactory completion of the Listing Report, and scheduling of a factory assessment in your facility.

MANUFACTURING AND PRODUCTION TESTS

Manufacturing and Production Tests shall be performed as required in this Report.

FOLLOW-UP SERVICE

Periodic unannounced audits of the manufacturing facility (and any locations authorized to apply the mark) shall be scheduled by Intertek. An audit report shall be issued after each visit. Special attention will be given to the following:

1. Conformance of the manufactured product to the descriptions in this Report.
2. Conformance of the use of the ETL mark with the requirements of this Report and the Certification Agreement.
3. Manufacturing changes.
4. Performance of specified Manufacturing and Production Tests.

In the event that the Intertek representative identifies non-conformance(s) to any provision of this Report, the Applicant shall take one or more of the following actions:

1. Correct the non-conformance.
2. Remove the ETL Mark from non-conforming product.
3. Contact the issuing product safety evaluation center for instructions.

10.1 Evaluation of Unlisted Components

Because Unlisted Components are uncontrolled, and they do not fall under a third party follow up program, Intertek may require these components to be tested and/or evaluated at least once annually, more often for certain components, as part of the independent certification process. The Unlisted Components in Section 5.0 require testing and/or evaluation as indicated.

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

11.1 Dielectric Voltage Withstand Test

Method

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

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

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

Test Equipment

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

The test equipment shall incorporate a voltmeter in the output circuit to indicate directly the applied test potential if the rated output of the test equipment is less than 500VA.

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

- 1 - a voltmeter in the primary circuit;
- 2 - a selector switch marked to indicate the test potential; or
- 3 - a marking in a readily visible location to indicate the test potential for test equipment having a single test potential output.

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

Products Requiring Dielectric Voltage Withstand Test:

<u>Product</u>	<u>Test Voltage</u>	<u>Test Time</u>
Between L/N and secondary output	4000Vac	1 s

The following changes are in compliance with the declaration of Section 8.1:

[illegible]