

## UL TEST REPORT AND PROCEDURE

<b>Standard:</b>	ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10)(Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance)
<b>Certification Type:</b>	Component Recognition
<b>CCN:</b>	QQHM2, QQHM8 (Power Supplies, Medical and Dental)
<b>Product:</b>	Medical power supply
<b>Model:</b>	GTM41080-1812-C1
<b>Rating:</b>	Input: 90-240Vac, 50-60Hz, 0.6A Output: 12Vdc, 1.25A
<b>Applicant Name and Address:</b>	GLOBTEK (HONG KONG) LTD UNIT 1402, BENSON TOWER 74 HUNG TO RD KWUN TONG KOWLOON HONG KONG

This is to certify that representative samples of the products covered by this Test Report have been investigated in accordance with the above referenced Standards. The products have been found to comply with the requirements covering the category and the products are judged to be eligible for Follow-Up Service under the indicated Test Procedure. The manufacturer is authorized to use the UL Mark on such products which comply with this Test Report and any other applicable requirements of UL LLC ('UL') in accordance with the Follow-Up Service Agreement. Only those products which properly bear the UL Mark are considered as being covered by UL's Follow-Up Service under the indicated Test Procedure.

The applicant is authorized to reproduce the referenced Test Report provided it is reproduced in its entirety.

UL authorizes the applicant to reproduce the latest pages of the referenced Test Report consisting of the first page of the Specific Technical Criteria through to the end of the Conditions of Acceptability.

Any information and documentation involving UL Mark services are provided on behalf of UL LLC (UL) or any authorized licensee of UL.

Prepared by: Jeffery Chan

Reviewed by: David Shih

#### **Supporting Documentation**

The following documents located at the beginning of this Procedure supplement the requirements of this Test Report:

- A. Authorization - The Authorization page may include additional Factory Identification Code markings.
- B. Generic Inspection Instructions -
  - i. Part AC details important information which may be applicable to products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of this Test Report.
  - ii. Part AE details any requirements which may be applicable to all products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of each Test Report.
  - iii. Part AF details the requirements for the UL Certification Mark which is not controlled by the technical standard used to investigate these products. Products are permitted to bear only the Certification Mark(s) corresponding to the countries for which it is certified, as indicated in each Test Report.

### Product Description

The equipment is a Medical Power Supply, type GTM41080-1812-C1, an electronic component mounted on PWB and housed in plastic enclosure. The enclosure was designed as 2 parts covering the top and bottom halves of the equipment and encapsulated together without opening, the AC inlet was fixed to enclosure by screw.

### Model Differences

N/A

### Technical Considerations

- Classification of installation and use : Recognized power adaptor, shall be determine in end use application.
- Device type (component/sub-assembly/ equipment/ system) : Component
- Intended use (Including type of patient, application location) : None
- Mode of operation : Continuous
- Supply connection : Appliance coupler
- Accessories and detachable parts included : None
- Other options include : None
- The product was investigated to the following additional standards:: CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) Edition 2 - Revision Date 2011/06/01, ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) - Edition 1 - Revision Date 2012/01/01, IEC 60601-1: 2005 + CORR.1 (2006) + CORR.2 (2007) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) - Edition 3 , EN60601-1:2006
- The product was not investigated to the following standards or clauses:: Clause 52.1, Programmable Electronic Systems (IEC 601-1-4), Clause 48, Biocompatibility (ISO 10993-1), Clause 36, Electromagnetic Compatibility (IEC 60601-1-2),
- The degree of protection against harmful ingress of water is:: IP67
- The mode of operation is:: Continuous
- The product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide:: No
- The product is classified only to the following hazards: Casualty, Fire, Shock.
- Software is relied upon for meeting safety requirements related to mechanical, fire and shock: No

### Engineering Conditions of Acceptability

For use only in or with complete equipment where the acceptability of the combination is determined by UL LLC. When installed in an end-product, consideration must be given to the following:

- This power supply has been judged on the basis of the required creepage and clearances in the Standards for Medical Electrical Equipment, IEC 60601-1: 2005 + CORR.1 (2006) + CORR.2 (2007) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) - Edition 3 Sub clause 8.9, ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) - Edition 1 - Revision Date 2012/01/01, Sub clause 8.9. And CAN/CSA-C22.2 No. 60601-1 (2008)

(Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) Edition 2 - Revision Date 2011/06/01

- The power supply was evaluated as 2 MOPP between Primary and Secondary.
- The Unit provide primary transformer (T1), which was incorporates as Class B, 130 degree C insulation system.
- The reference voltage for Dielectric Voltage Test in End Product: 240Vrms, 640Vpk for T1.
- The leakage current test should be evaluated in end product again.
- The power supply is evaluated as Class II equipment with SELV output.
- End product Risk Management Process to include consideration of requirements specific to the Power Supply.
- End product Risk Management Process to consider the need for simultaneous fault condition testing.
- End product Risk Management Process to consider the need for different orientations of installation during testing.
- End product to determine the acceptability of risk in conjunction to insulation to resistance to heat, moisture, and dielectric strength.
- End product to determine the acceptability of risk in conjunction to the movement of components and conductors as part of the power supply.
- End product to determine the acceptability of risk in conjunction to the routing of wires away from moving parts and sharp edges as part of the power supply.
- Temperature Test was conducted without Test Corner. End product to determine the acceptability of risk in conjunction to temperature testing without test corner as part of the power supply.
- End product to determine the acceptability of risk in conjunction to the Cleaning and Disinfection Methods as part of the power supply.
- End product to determine the acceptability of risk in conjunction to the Leakage of Liquids as part of the power supply.
- End product to determine the acceptability of risk in conjunction to the Arrangement of Indicators as part of the power supply.
- End product to determine the acceptability of risk in conjunction to the results of Mechanical Testing conducted as part of the power supply.
- End product to determine the acceptability of risk in conjunction to the selection of components as it pertains to the intended use, essential performance, transport, storage conditions as part of the power supply.
- The end-product evaluation shall ensure that the requirements related to Accompanying Documents, Clause 7.9 are met.
- The touch time for external enclosure isn't determined by the client, end product shall consider it according to client's definition.
- Compliance with the requirements for EMC shall be evaluated for the end use product.
- Overcurrent releases of adequate breaking capacity must be employed in the end product
- The end-use product shall ensure that the power supply is used within its ratings.
- The risk management requirements of the standard were not addressed in this project, it shall be considered in end-product.
- The Max. working temperature of this power supply is 50 Deg C. Additional test may require if the temperature is higher than 50 Deg C.

- Maximum ambient temperature of this power supply is 50 deg C at full load.
- Clearance distance was evaluated for operating altitude up to 5000m above sea level.
- For IP67, the AC cord set is used below: AC cord, Model SVT and SJT by SUZHOU TONGYUAN ELECTRIC WIRE & CABLE CO LTD. Plug of AC cord, Model SM001 by SELF-MAN INDUSTRIAL CO. Appliance Coupler of AC cord, Model SM006 by SELF-MAN INDUSTRIAL CO ,
- For IP67 without AC cord set, the AC inlet part should be evaluated in order to fulfill IP67 requirement.

#### Additional Information

The risk management requirements of the standard were not addressed in this project, it shall be considered in end-product.


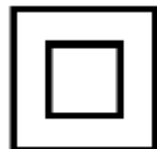
UL project 4786338356

- Add the alternate AC inlet, Model 6102-91 by SCHURTER (E96454) and IP 67 (including adding AC power cord for IP test)

#### Additional Standards

The product fulfills the requirements of: EN60601-1:2006

#### Markings and instructions

Clause Title	Marking or Instruction Details
Company identification	Classified or Recognized company's name, Trade name, Trademark or File
Model	Model number
Supply Connection	Voltage range, ac/dc, phases if more than single phase
Direct current	
Supply Frequency	Rated frequency range in hertz
Class II equipment	
Power Input	Amps, VA, or Watts
Output	Rated output voltage, power, frequency.

#### Special Instructions to UL Representative

N/A

Production-Line Testing Requirements			
<b><u>Test Exemptions</u></b> - The following models are exempt from the indicated test			
Model	Grounding Continuity	Dielectric Voltage Withstand	Patient Circuit Dielectric Voltage Withstand
-	Exempt	Necessary	Exempt
<b><u>Solid-State Component Test Exemptions</u></b> - The following solid-state components may be disconnected from the remainder of the circuitry during either Dielectric Voltage Withstand Test:			
Component			
N/A			
<b><u>Sample and Test Specifics for Follow-Up Tests at UL</u></b>			
The following tests shall be conducted in accordance with the Generic Inspection Instructions			
Plastic Enclosure or Part	Test	Sample(s)	Test Specifics
N/A			

**TABLE: List of Critical Components**

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
Plastic Enclosure	SABIC INNOVATIVE Plastics China Ltd. (E45329)	C2950	Min 2.0mm thick, flame class V-1, 85 Deg C, See enclosure 4-07 for details of enclosure dimension.	QMFZ2 /8	UL
AC inlet	SCHURTER (E96454)	6102-31	Rated 15A,250Vac	AXUT2/8	UL/cUL
AC inlet - alternate	SCHURTER (E96454)	6102-91	Rated 15A,250Vac	AXUT2/8	UL/cUL
AC cord (Optional as it is for IP67)	SUZHOU TONGYUAN ELECTRIC WIRE & CABLE CO LTD	SVT, SJT	Min. 300V, min.60 Deg C, min.18AWg	ZJCZ/ZJCZ7	UL / CUL (E230449)
-Plug of AC cord (Optional as it is for IP67)	SELF-MAN INDUSTRIAL CO	SM001	10A, 125V	ELBZ/ELBZ7	UL / CUL (E119543)
- Appliance Coupler of AC cord (Optional as it is for IP67)	SELF-MAN INDUSTRIAL CO	SM006	10A, 125V	ELBZ/ELBZ7	UL / CUL (E119543)
Input wire	Various	Various	300V, 80 degree C, 18 AWG or better	AVLV2/8 or ZJCZ	UL/cUL
PCB material	Various	Various	Min. V-1 min. 105 Deg C	ZPMV2	UL
Fuse (F1)	Conquer Electronics Co.Ltd (E82636)	MST	T1.6A/250Vac	JDYX2/8	UL/cUL
Fuse (F1) Alternate	Ever Island Electric Co Ltd & Walter Electric (E56092)	2010	T1.6A/250Vac	JDYX2/8	UL/cUL
Fuse (F1) Alternate	Various	Various	T1.6A/250Vac	JDYX/7	UL/cUL
Bridging diode (D1, D2,	--	--	Min.1A, Min. 600V	--	--

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
D3, D4)					
Varistor, (MOV1) after fuse (optional)	TKS (E314979)	TVR10471, TVR07471, TVR14471	300Vac	VZCA2/8	UL/cUL
Varistor, (MOV1) after fuse (optional)	Centra (E316325)	CNR07D471K, CNR10D471K, CNR14D471K	300Vac	VZCA2/8	UL/cUL
Varistor, (MOV1) after fuse (optional)	JOYIN (E325508)	7N471K, 10N471K, 14N471K	300Vac	VZCA2/8	UL/cUL
Varistor, (MOV1) after fuse (optional)	Success Electronics Co Ltd (E330256)	SVR07D471K, SVR10D471K, SVR14D471K	300Vac	VZCA2/8	UL/cUL
Varistor, (MOV1) after fuse (optional)	Brightking Shenzhen Co Ltd (E327997)	471KD07, 471KD10, 471KD14	300Vac	VZCA2/8	UL/cUL
Varistor, (MOV1) after fuse (optional)	Ceramate (E315429)	GNR07D471K, GNR10D471K, GNR14D471K	300Vac	VZCA2/8	UL/cUL
Varistor, (MOV1) after fuse (optional)	Walsin (E309297)	07D471K, 10D471K, 14D471K	300Vac	VZCA2/8	UL/cUL
Varistor, (MOV1) after fuse (optional)	Hongzhi (E324904)	HEL-07D471K, HEL-10D471K, HEL-14D471K	300Vac	VZCA2/8	UL/cUL
Varistor, (MOV1) after fuse (optional)	New Future (E323753)	07D471K, 10D471K, 14D471K	300Vac	VZCA2/8	UL/cUL
X cap (CX1) (optional)	Cheng Tung (E193049)	CTX	Max. 0.22 uF, min. 250 Vac, 100 degree C Min (X2 or X1)	FOWX2/8	UL/cUL
Alternative	UTX (E183780)	HQX	Max. 0.22 uF, Min. 275Vac, 100 degree C Min (X2)	FOWX2/8	UL/cUL
Alternative	Dain (E147776)	MPX, NPX	Max. 0.22 uF, min. 250 Vac, 100 degree C Min	FOWX2/8	UL/cUL



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Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
			(X2)		
Alternative	Welson (E104572)	WD	Max. 0.22 uF, min. 250 Vac, 100 degree C Min (X2)	FOWX2/8	UL/cUL
Alternative	Sinhua Electronics (Huzhou) Co. Ltd. (E237560)	MPX	Max. 0.22 uF, min. 275 Vac, 100 degree C Min (X2)	FOWX2/8	UL/cUL
Alternative	Jiangsu Xinghua Huayu Electronics Co., Ltd. (E311166)	MPX	Max. 0.22 uF, min. 275 Vac, 100 degree C Min .(X2)	FOWX2/8	UL/cUL
X cap (CX1) Alternative	HongZhi (E192572)	MPX	Max. 0.22 uF, min. 250 Vac, 100 degree C Min .(X2)	FOWX2/8	UL/cUL
Bulk Capacitor (C1)	--	--	Rated Min 33uF Min 400V, Min 105Deg C	--	--
Y capacitor (CY1,CY2) (optional)	TDK (E37861)	CD	Max. 2200pF, min. 250 Vac, 100 degree C min. (Y1)	FOWX2	UL
Alternative	Walsin (E146544)	AH	Max. 2200pF, min. 250 Vac, 100 degree C min. (Y1)	FOWX2/8	UL/cUL
Alternative	Jya-Nay (E201384)	JN	Max. 2200pF, min. 250 Vac, 100 degree C min. (Y1)	FOWX2/8	UL/cUL
Alternative	Murata (E37921)	KX	Max. 2200pF, min. 250 Vac, 100 degree C min.(Y1)	FOWX2	UL
Alternative	Success (E114280)	SB, SE	Max. 2200pF, min. 250 Vac, 100 degree C min.(Y1)	FOWX2	UL

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
Alternative	Welson (E104572)	WD	Max. 2200pF, min. 250 Vac, 100 degree C min.(Y1)	FOWX2/8	UL/cUL
Alternative	HAOHUA ELECTRONIC CO (E233106)	CT7	Max. 2200pF, min. 250 Vac, 85 degree C min.(Y1 )	FOWX2/8	UL/cUL
Alternative	KUNSHAN WANSHENG ELECTRONICS CO LTD (E249006)	CT7	Max. 2200pF, min. 250 Vac, 85 degree C min.(Y1 )	FOWX2/8	UL/cUL
Alternative	JERRO ELECTRONICS CORP (E333001)	JX- series	Max. 2200pF, min. 250 Vac, 85 degree C min.(Y1 )	FOWX2/8	UL/cUL
Line filter(LF1)	Various	Various	130 Deg C	--	--
-Core	--	--	Ferrite core, approximate overall 14.25 mm by 9.77mm by 2.84 mm.	--	--
- Wire	--	--	130 Deg C, MW -75 or MW28 Type.	OBMW2	UL
Optocoupler (U1)	Sharp (E64380)	PC817	Rated min. 110degC Provide min 5000Vac isolation test voltage rating.	FPQU2/8	UL/cUL
Optocoupler (U1) Alternative	Everlight ((E214129)	EL817	Rated min. 110degC Provide min 5000Vac isolation test voltage rating.	FPQU2/8	UL/cUL
Optocoupler (U1) Optocoupler (U1) Alternative	Liteon ( E113898)	LTV-817	Rated min. 115degC Provide min 5000Vac isolation test voltage rating.	FPQU2/8	UL/cUL
Optocoupler (U1) Alternative	Cosmo (E169586)	K1010 ,KP1010	Rated min. 115degC Provide min 5000Vac isolation test voltage rating.	FPQU2/8	UL/cUL
Optocoupler (U1) Alternative	Fairchild (E90700)	H11A817B F0D817B	Rated min. 110degC Provide min 5000Vac isolation test voltage rating.	FPQU2/8	UL/cUL
Optocoupler (U1) Alternative	Bright Led Electronics Corp. (E236324)	BPC-817	Rated min. 125degC Provide min 5000Vac isolation test voltage rating.	FPQU2/8	UL/cUL

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
Resistance(R1)	--	--	SMD type, rated Max.1.5M ohm, min.1/8 W.	--	--
Resistance(R2)	--	--	SMD type, rated Max. 1.5M ohm, min.1/8 W.	--	--
Transistor (Q1)	--	--	Rated minimum 600 V, Min.4A. Secured to Heat Sink, by metal clamp.	--	--
Transformer (T1)	SHAN DONG BOAM ELECTRIC CO LTD	XF00579A	(OBJY2) Class B	--	--
- Insulation system used in T1	SHAN DONG BOAM ELECTRIC CO LTD (E252329)	BOAM-01	Class 130 (B) Insulation System	OBJY2/8	UL
-Core used in T1	--	--	Ferrite core ,approximate overall 22.08mm by 5.67mm by 9.35 mm	--	--
-Primary winding used in T1	Various	Various	Polyurethane with or without overcoat Polyamide, 130 Deg C min.	OBMW2	UL
-Secondary wire of T1	Furukawa (E206440)	TEX-E	Rated 130 Deg C, Triple insulated wire	OBJT2	UL
-Bobbin for T1	Sumitomo Bakelite CO.,LTD (E41429)	PM-9820	Phenolic, 150deg C, V-0	QMFZ2/8	UL/cUL
-Insulation tape wrapped used in T1	YAHUA(E165111)	PZ	Rated 130 degC.	OANZ2	UL
-Varnish used in T1	NOROO PAINT&COATINGS CO.,LTD(E93947)	DVB-2085(C), DVB-2085(1)	Rated 130 degC.	OBOR2	UL
-Tube	GREAT HOLDING INDUSTRIAL CO LTD (E156256)	TFL	VW-1. Rated 150V, 200 degC for TFL	YDTU2	UL
Transformer (T1) (Alternate)	GlobTek/ WUXI ZHONGTONG ELECTRONICS CO LTD	XF00579A	(OBJY2) Class B	--	--
- Insulation system used in T1	GLOBTEK INC (E243347)	GTX-130-TM	Class 130 (B) Insulation System	OBJY2	UL
- Insulation system used	WUXI ZHONGTONG	ZT-130	Class 130 (B) Insulation System	OBJY2/8	UL

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
in T1 (Alternate)	ELECTRONICS CO LTD (E315275)				
- Primary winding used in T1	Various	Various	Polyurethane with or without overcoat Polyamide, 130 Deg C min.	OBMW2	UL
-Secondary winding used in T1	GREAT LEOFLON INDUSTRIAL CO LTD (E211989)	TRW(B)	Rated 130 Deg C Triple insulated wire	OBJT2	UL
-Secondary winding used in T1 (Alternate)	COSMOLINK CO LTD (E213764)	TIW-M	Rated 130 Deg C Triple insulated wire	OBJT2	UL
-Bobbin for T1 (From Glotek and Zhongtong)	Changchun Plastics (E59481)	T375J T373J T375HF	Phenolic, 150 Deg C, V-0. For the type T373J with color BK and BN, the min thickness is 2.0mm.	QMFZ2/8	UL
-Bobbin for T1 (From Glotek and Zhongtong) (Alternate)	Sumitomo Bakelite CO.,LTD (E41429)	PM-9820	Phenolic, 150DegC, V-0	QMFZ2/8	UL
- Core used in T1	--	--	Ferrite core ,approximate overall 22.08mm by 5.67mm by 5.7 mm	--	--
- Insulation Tape used in T1	JINGJIANG YAHUA (E165111)	PZ, CT	Rated 130 Deg C	OANZ2	UL
- Insulation Tape used in T1 (Alternate)	JINGJIANG JINGYI ADHESIVE PRODUCT CO LTD(E246950)	JY25-A	Rated 130 Deg C	OANZ2	UL
- Varnish used in T1	WU JIANG TAIHU INSULATING MATERIAL CO LTD(E228349)	T-4260(a)	Rated 130 Deg C	OBOR2	UL
- Tube	GREAT HOLDING INDUSTRIAL CO LTD (E156256)	TFL, TFT	VW-1. Rated 150V, 200 Deg C for TFL; Rated 300V, 200 Deg C for TFT	YDPU2	UL
- Tube (Alternate)	SHENZHEN WOER	WF	VW-1. Rated 600V, 200 Deg C	YDPU2/8	UL/cUL

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
	HEAT-SHRINKABLE MATERIAL CO LTD (E203950)				
Heat Sink - HS1	--	--	Aluminum. Approximate overall dimension 26mm by 17mm, 1.5mm thick, secured to PWB by soldering	--	--
Insulation tape provided on HS1(optional)	CHANG SHU LIANG YI TAPE INDUSTRY CO LTD (E246820)	LY-XX	Rated 130 Deg C	OANZ2	UL
Insulation tape provided on HS1 (Alternate)	3M COMPANY ELECTRICAL MARKETS DIV (EMD) (E17385)	1350T-1, 44	Rated 130 Deg C	OANZ2	UL
Insulation tape provided on HS1 (Alternate)	YAHUA ADHESIVE TAPE CO LTD (E165111)	CT	Rated 130 Deg C	OANZ2	UL
Insulation tape provided on HS1 (Alternate)	SYMBIO INC (E50292)	35660Y	Rated 130 Deg C	OANZ2	UL
Output wire	Various	Various	300V, 80 Deg C, 24AWG or better	AVLV2/8 or ZJCZ	UL/cUL
Potting Compound(filled within unit, including the potting on AC inlet)	SUZHOU POCHELY ELECTRONIC MATERIAL CO LTD(E304947)	HB-5225A/B	Rated V-0, minimum 90 Deg C	QMFZ2	UL
Label (optional)	Dongguan Xianquan Printing Co Ltd( MH27594)	XQ03	Rated min 80 Deg C Suitable for use on the plastic enclosure	PGDQ2	UL
Label (optional) (Alternate)	Fan JA Paper Printing Co Ltd( MH19546 )	FJ-03-3	Rated min 80 Deg C Suitable for use on the plastic enclosure	PGDQ2/8	UL/cUL
Label (optional) (Alternate)	Fan JA Paper Printing Co Ltd( MH19546 )	FJ07	Rated min 80 Deg C Suitable for use on the plastic enclosure	PGDQ2/8	UL/cUL

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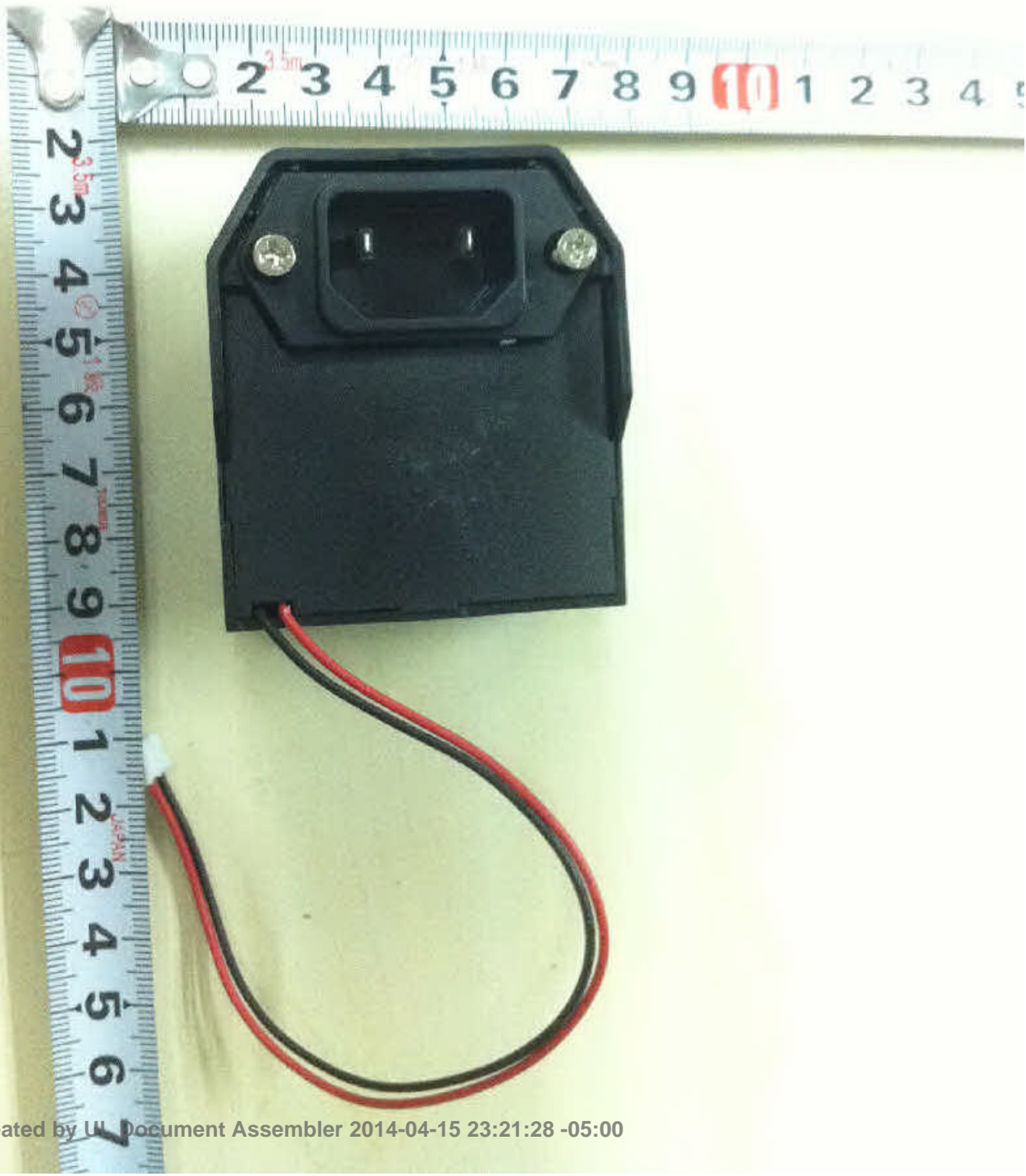
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Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
Label (optional) (Alternate)	Dongguan Xianquan Printing Co Ltd( MH47303 )	XQ004-B	Rated min 80 Deg C Suitable for use on the plastic enclosure	PGDQ2/8	UL
Label (optional) (Alternate)	E-Lin Adhesive ( MH45549 )	EL-15	Rated min 80 Deg C Suitable for use on the plastic enclosure	PGDQ2/8	UL/cUL
Label (optional) (Alternate)	SHENZHEN CORWIN PRINTING CO LTD(MH47077)	CW-01	Rated min 80 Deg C Suitable for use on the plastic enclosure	PGDQ2/8	UL/cUL
Label (optional) (Alternate)	YUEN CHANG SPECIAL PRINTING (SHENZHEN) CO LTD (MH29752)	JL-08	Rated min 80 Deg C Suitable for use on the plastic enclosure	PGDQ2	UL/cUL

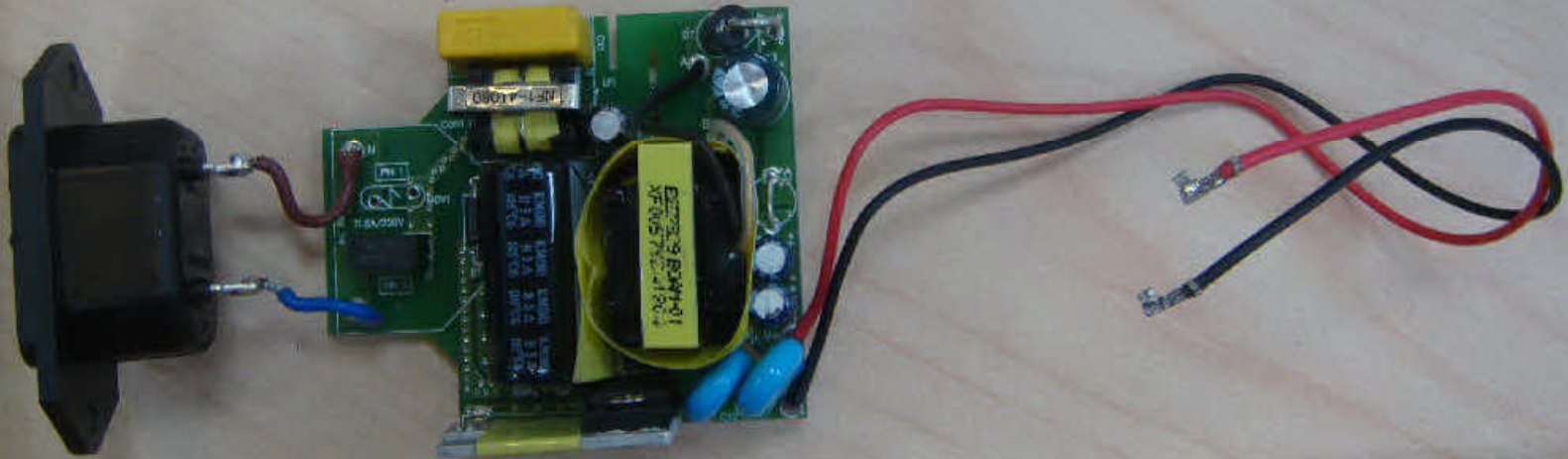
## **Enclosures**

<u>Type</u>	<u>Supplement Id</u>	<u>Description</u>
Collateral		
Particular		
Photographs	3-01	Top View of the unit
Photographs	3-02	Bottom View of the unit
Photographs	3-03	Top view of the unit / No potting compound - without enclosure
Photographs	3-04	Bottom view of the unit / No potting compound - without enclosure
Photographs	3-09	Top View of the unit (alternate AC inlet)
Diagrams	4-01	Specification - Transformer T1 from BOAM
Diagrams	4-02	Specification - Transformer T1 from Glob Tek
Diagrams	4-03	Specification - Transformer T1 from ZhongTong
Diagrams	4-05	Specification - Power Supply GTM41080-1812-C1
Diagrams	4-06	Dimension drawing - Top cover
Diagrams	4-07	Dimension drawing - Enclosure
Diagrams	4-08	Dimension drawing - Heatsink HS1
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Manuals		
Miscellaneous	7-01	Label
Miscellaneous	7-02	Client Declaration table
Miscellaneous	7-03	Fuse specification (type MST) - 1
Miscellaneous	7-04	Fuse specification (type:MST) - 2
Miscellaneous	7-05	Fuse specification (Type 2010)
Miscellaneous	7-06	Multiple factories agreement















## 零件承认书 Material Approval

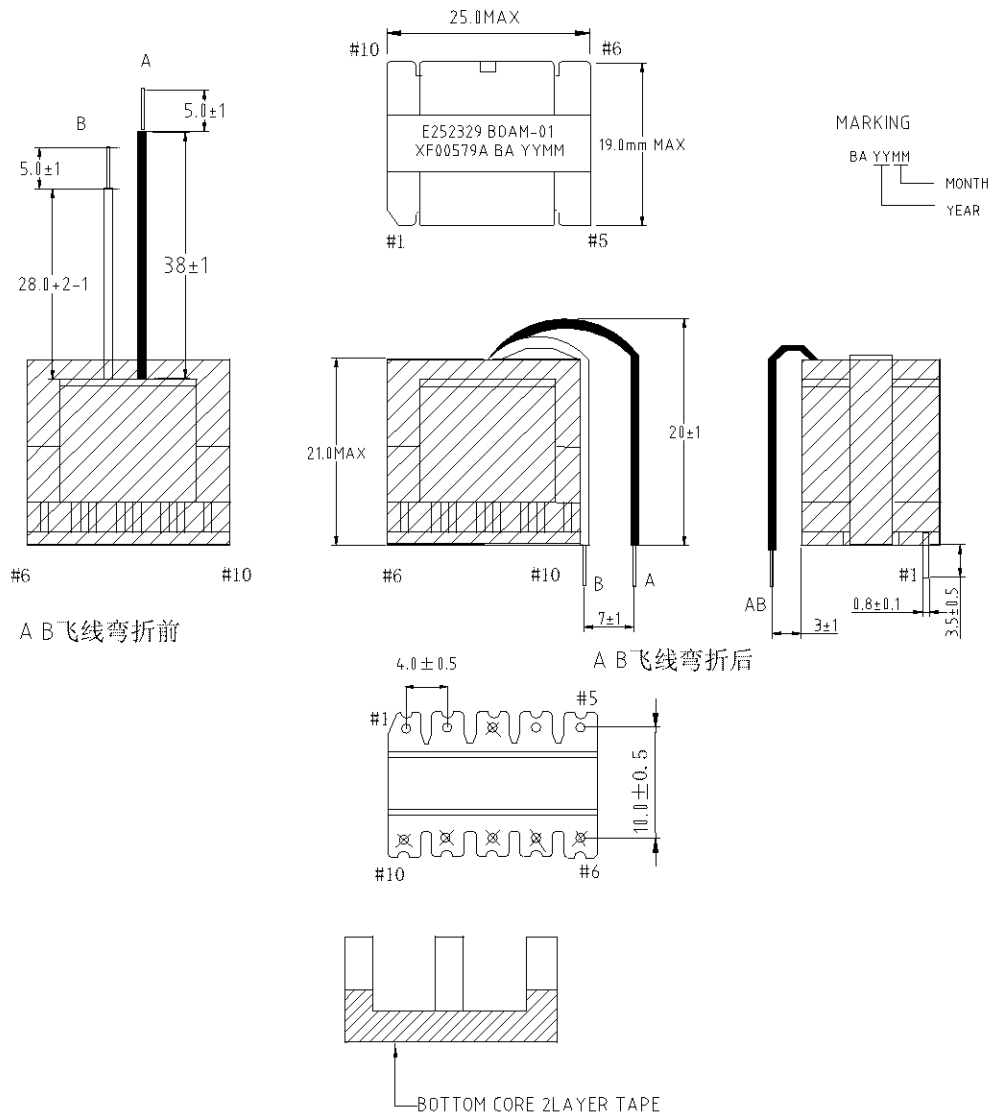
制造商: Manufacturer	山东宝岩电气有限公司
供应商: Supplier	山东宝岩电气有限公司 SHAN DONG BOAM CO.,LTD
供应商料号: Supplier P/N	320-01951403 (R)
名称: Part Name	TRANSFORMER
品名/规格: SPEC	XF00579A
GlobTek料号: GlobTek P/N	320-01951403
Edition No: 版本	C

作成: Made by	确认: Check	承认: Approval
孙小丽	黄丽红	潘秀丽
PS承认章: Approval Stamp	RD承认章: Approval Stamp	QC承认章: Approval Stamp

SPECIFICATION

CUSTOMER	GLOBTEK(SUZHOU)	PART NAME	TRANSFORMER
MODEL NO.	EE2218	PART NO.	320-01951403(R)

1 DIMENSION(mm)



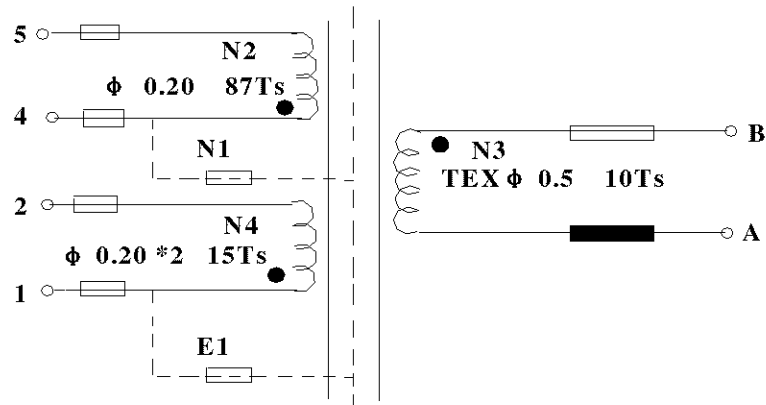
SPEC NO.	KF-120309-C	DATE	2012.03.09	SHEET NO.	1	
NO.	DATE	REVISION	CHECKED	DESIGN	CHECK	APPROVAL

SHANDONG BOAM ELECTRIC CO.,LTD

SPECIFICATION

CUSTOMER	GLOBTEK(SUZHOU)	PART NAME	TRANSFORMER
MODEL NO.	EE2218	PART NO.	320-01951403(R)

2 SCHEMATIC:



- \* THE “●” MARKS ARE START POINT
- \* REMOVE PIN :3#, 6#, 7#, 8#, 9#,10#
- \* TEFLON TUBE:  (A; BLACK; B:WHITE)

SPEC NO.	KF-120309-C	DATE	2012.03.09	SHEET NO.	2	
NO.	DATE	REVISION	CHECKED	DESIGN	CHECK	APPROVAL

SHANDONG BOAM ELECTRIC CO

## 1. NOTES:

DIMENSIONS ARE IN MM UNLESS SPECIFIED OTHERWISE.



## 2. ELECTRICAL SPECIFICATIONS:

INPUT VOLTAGE:	85-264	VAC
INPUT CURRENT:	0.6	Amp RMS MAX
INPUT FREQUENCY:	47-63	Hz
OUTPUT VOLTAGE:	12	VDC
OUTPUT CURRENT:	1.25	A, NO MINIMUM LOAD REQUIRED TO MAINTAIN OUTPUT VOLTAGE REGULATION
OUTPUT POWER (RATED):	15	WATTS MAX
OUTPUT LOAD REGULATION:	+/- 5% MEASURED AT O/P CONNECTOR	
LINE VOLTAGE REGULATION:	+/- 1% TYPICAL MEASURED AT THE OUTPUT CONNECTOR	
OUTPUT RIPPLE (PEAK TO PEAK):	120mV MAX. MEASURED AT 20 MHz BANDWIDTH WITH 0.1 $\mu$ f CERAMIC CAPACITOR IN PARALLEL WITH 10 $\mu$ f ELECTROLYTIC CAPACITOR CONNECTED AT THE END OF OUTPUT CONNECTOR AT NOMINAL LINE	
TURN-ON/TURN-OFF OVERSHOOT:	5% MAXIMUM, 1mS TYPICAL RECOVERY TIME FOR 25% STEP LOAD	
TURN-ON DELAY:	1 SECOND, TYPICAL	
HOLD-UP TIME:	8mS TYPICAL AT NOMINAL INPUT VOLTAGE AND FULL LOAD	
INRUSH CURRENT:	30A TYPICAL AT 115VAC INPUT AND 60A TYPICAL AT 230 VAC INPUT	

## PROTECTION

OVER-VOLTAGE:	PROTECTED WITH 16V ZENER CLAMP ACROSS OUTPUT
SHORT CIRCUIT:	PROTECTED, UNIT WILL RECOVER UPON REMOVAL OF FAULT
INPUT:	INPUT LINE FUSING

## SAFETY:

DIELECTRIC WITHSTAND VOLTAGE:	5656	VDC FROM PRIMARY TO SECONDARY
EARTH LEAKAGE:	<100 $\mu$ A AT 264 VAC INPUT VOLTAGE, NORMAL CONDITION	
AIR CREEPAGE/ CLEARANCE:	8 mm OR AS REQUIRED IN EN60601-1 STANDARD, 3-rd EDITION	

## APPROVALS

SAFETY APPROVAL(PENDING):	EN60601-1:2006 MEDICAL ELECTRICAL EQUIPMENT PART I: GENERAL REQUIREMENT FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE, 3-rd EDITION
---------------------------	--

EMI:	COMPLIES WITH EN55011 CLASS B AND FCC PART 15 CLASS B, WHEN TESTED WITH RESISTIVE LOAD, BOTH CONDUCTED AND RADIATED EMI TESTED TO COMPLY WITH EN60601-1-2: 2007 MEDICAL ELECTRIC EQUIPMENT PART 1-2: GENERAL REQUIREMENTS FOR BASIC SAFETY, ESSENTIAL PERFORMANCE. COLLATERAL STANDARD: ELECTROMAGNETIC COMPATIBILITY
------	--

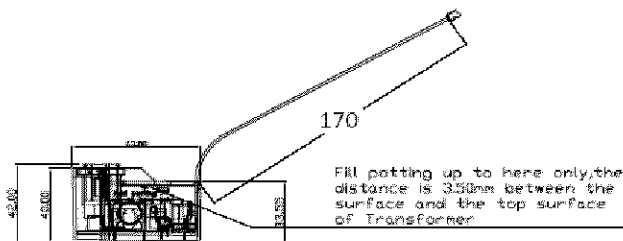
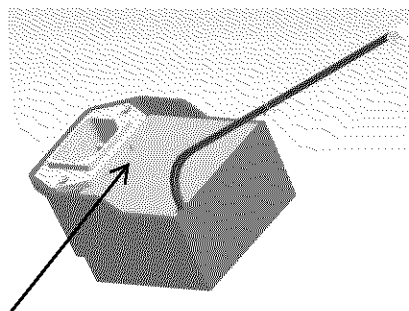
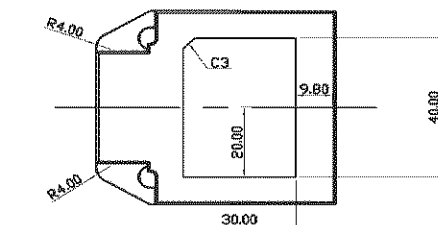
EFFICIENCY:	ENERGY STAR VERSION 2.0, LEVEL V COMPLIES TO SECTION 301 OF THE ENERGY INDEPENDENCE AND SECURITY ACT (EISA) CECP TIER 2 (CHINA), MEPS TIER 2 (AUSTRALIA), CODE OF CONDUCT (EUROPE)
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## OTHERS

MTBF:	200,000 HOURS AT 25°C AMBIENT TEMPERATURE, 5W LOAD
OPERATING TEMPERATURE:	0°C TO 50°C AMBIENT TEMPERATURE
HUMIDITY:	0% TO 90% RELATIVE HUMIDITY
STORAGE TEMPERATURE:	-20°C TO +55°C
RoHS:	COMPLIES WITH EU 2002/95/EC AND CHINA SO/T 11363-2006



MATERIAL	PC+ABS(C2950), 94V-0, RoHS
COLOR:	BLACK
DIMENSIONS:	SEE BELOW



NOTED:  
Material : PC+ABS (C2950), 94V-0, BLACK, Rohs.

FILLED WITH BLACK POTTING COMPOUND UL94 V-0

PROPRIETARY INFORMATION:

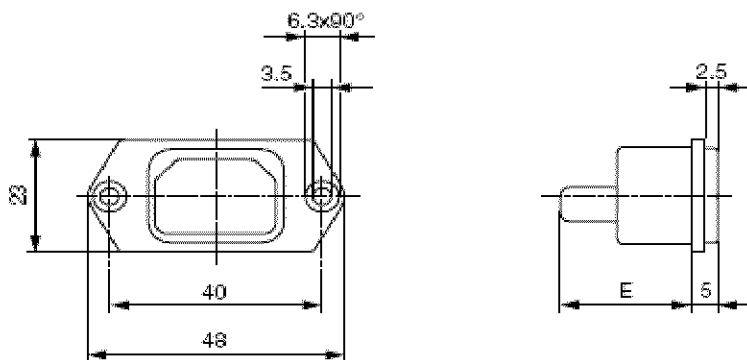
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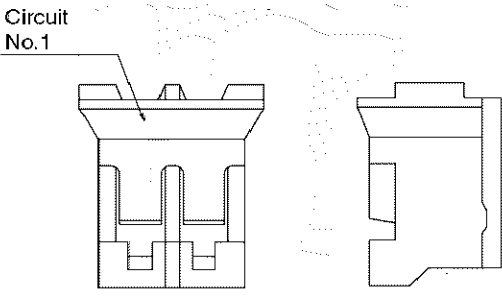
4. INPUT CONNECTOR:

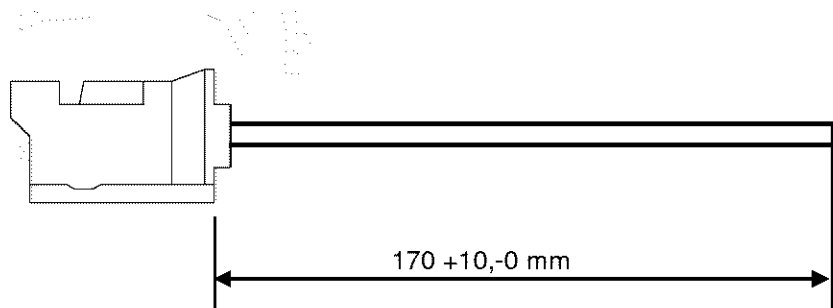
STANDARD BLACK COLOR

SCHURTER P/N: 6102-3 OR APPROVED EQUIVALENT

TYPE: IEC60320 C18

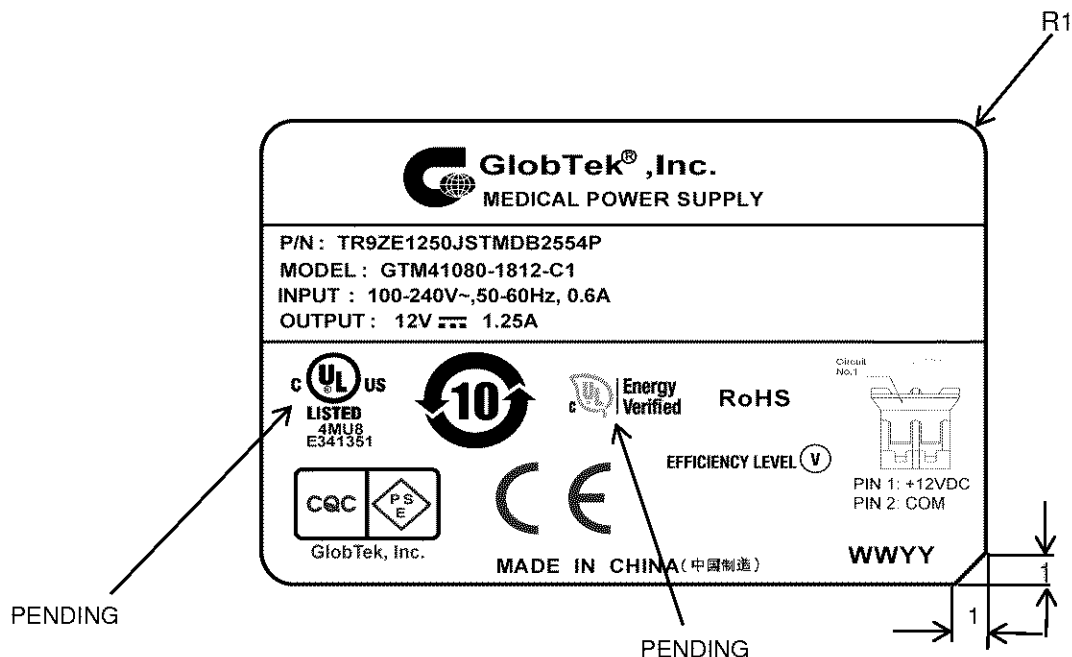


5. OUTPUT CORD AND CONNECTOR:		
ACTUAL CONNECTOR, OVERMOLDS, FERRITES, MAY VARY SLIGHTLY FROM THE PICTURE BELOW		
	EQUIVALENT	Y / N
<div>  <p>Circuit No. 1</p> </div>	CABLE TYPE	UL 1007
	CABLE LENGTH	170 +10,-0 mm
	WIRE GAUGE (AWG)	24 AWG
	HANK DIMENSION	N/A
	CABLE / CONNECTOR OVERMOLD COLOR	N/A
	FERRITE TYPE / DIMENSION	N/A
	FERRITE # OF TURNS	N/A
	FERRITE DIMENSION FROM STRAIN RELIEF	N/A
	FERRITE DIMENSION FROM PLUG	N/A
	PLUG TYPE	Y JST PHR-2
	OVER MOLD ORIENTATION	N/A
	PLUG DIMENSIONS	N/A
	BARREL PLUG INTERNAL SPRING CLIP	NO
	BARREL PLUG LOCKING NOTCH	NO
	POLARITY	PIN 1: (+), PIN 2: COM
	STRIP LENGTH	N/A
	TIN LENGTH	N/A
	ADDITIONAL REQUIREMENTS	N/A



# 6. LABEL:

MATERIAL	FLAT THERMAL TRANSFER, IMPRINTABLE, POLYESTER SHEET
BACKGROUND COLOR:	BLACK
TEXT COLOR:	WHITE OR SILVER
LABEL WIDTH: (mm)	39.8 +0,-0.2 mm
LABEL LENGTH: (mm)	29.8+0,-0.2 mm



ACTUAL POSITIONING OF SYMBOLS AND TEXT  
IS SUBJECT TO CHANGE AT TIME OF MANUFACTURE

## 7. PACKAGING:

GIFT BOX SIZE:

80 x 65 x 53 mm

GIFT BOX COLOR:

WHITE

CARTON SIZE:

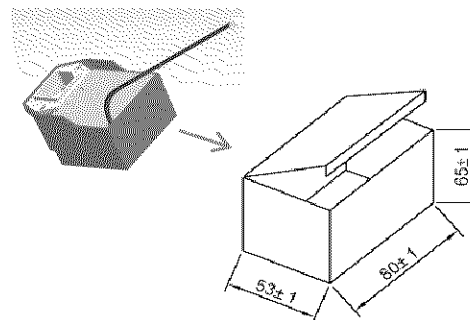
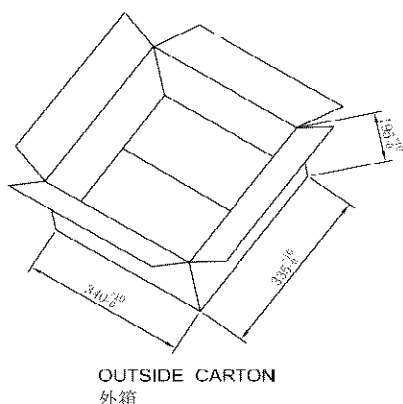
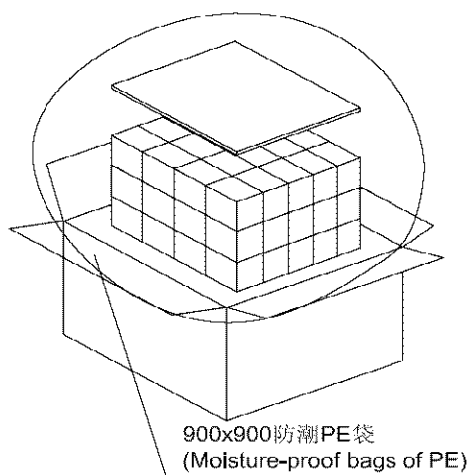
335 x 340 x 195 mm

QUANTITY PER CARTON:

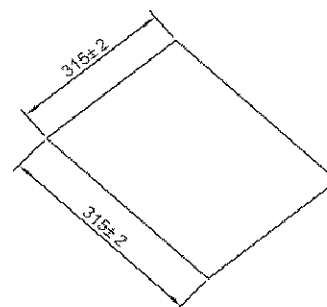
60 pcs

G.W.

TBA



GIFT BOX 礼品盒 80(L)X53(W)X65(H)



PARTITION 隔板

4	1PCS	OUTER CARTON	413-01160001(R)
3	4PCS	PARTITION	412-01160001(R)
2	60PCS	GIFTBOX	411-01140001(R)
1	1PCS	POLY BAG	465-00900900(R)

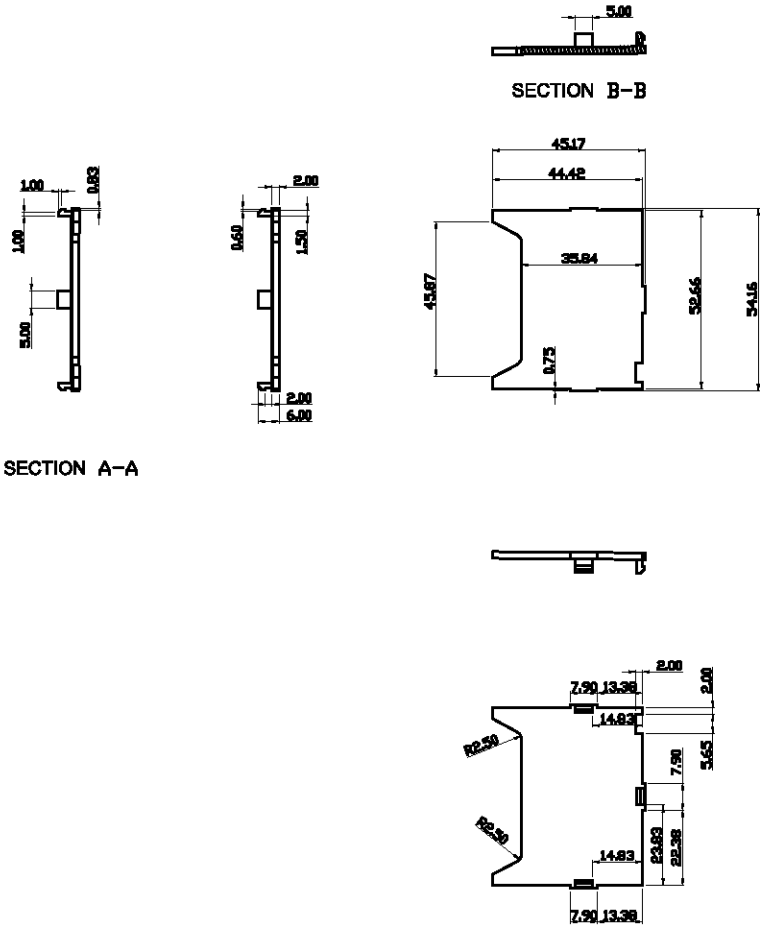
### Note:

- 1.outside carton: 6mm corrugated fiberboard,dim. measured exterior face  
外箱: 6mm瓦楞纸, 尺寸外控
- 2.partition: 3mm corrugated fiberboard  
隔板: 3mm瓦楞纸
- 4.gift box: art paper, dim. measured exterior face,no printing on the outside.  
礼盒: 铜板纸, 尺寸外控
- 5.actual dim. of outside carton subject to change at time of manufacture  
外箱的实际尺寸厂商可以根据实配在公差范围内进行调整

<div> <div>8. INTERCHANGEABLE BLADE INSERTION INSTRUCTION:</div> <div>ACTUAL CASE MAY VARY SLIGHTLY FROM THE PICTURE BELOW</div> </div>						
<div>CHINA RoHS SELF DISCLOSURE TABLE</div>						
<div> <div>有毒有害物质或元素名称及含量标准形式</div> <div>Name and concentration of hazardous substance or element in product</div> </div>						
零件名 Name of part	剧毒有害物质或元素 Hazardous substance or element					
	铅 Pb	汞 Hg	镉 Cd	六价铬 Cr(VI)	多溴联苯 PBB	多溴二苯醚 PBDE
Diode (110-220AB) 二极管	X	○	○	○	○	○
SMD resistor SMD 电阻	X	○	○	○	○	○
SMD Diode SMD 二极管	X	○	○	○	○	○
PLUG 直流输出端子	X	○	○	○	○	○
AC PIN 交流输入端子	X	○	○	○	○	○
<div> <div>○: 表示该有毒有害物质在这部件中所有同质材料中的含量均在SJ/T 11363-2006规定的限量要求以下。</div> <div>○: refers to the concentration of this hazard substance in the all homogenous materials in this part is below the concentration limit as stipulated in the standard SJ/T 11363-2006.</div> </div>						
<div> <div>X: 表示该有毒有害物质至少在这部件中的某一同质材料中的含量超出 SJ/T 11363-2006规定的限量要求。</div> <div>X: refers to the concentration of this hazard substance at least in a homogenous material is higher than the concentration limit as stipulated in the standard SJ/T 11363-2006.</div> </div>						

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REVISION			
REV	DESCRIPTION	DATE	APPROVED
A	Initial Release	2011.12.21	JB
B	Adjusted it that match the Enclosure and Inlet	2012.02.03	JB

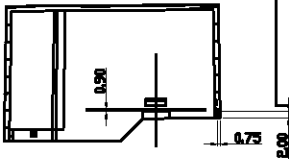


Tolerance table			
RANGE	GRADE 1	GRADE 2	GRADE 3
0~4	+/-0.05	+/-0.1	+/-0.2
4~16	+/-0.08	+/-0.15	+/-0.3
16~64	+/-0.12	+/-0.25	+/-0.5
64~250	+/-0.25	+/-0.4	+/-0.8

NOTED:  
Material : PC+ABS (C2950), 94V-0, BLACK, Rohs.

DASH NO		PART NO	REV.	DESCRIPTION	NOTES	
460-01300004 (R)						
		TOLERANCES:  GRADE 1		<b>GlobTek(Suzhou), Co.,Ltd</b> Tel: +86-512-6279-0301 Fax: +86-512-6279-0355 Web: www.globtek.cn		
INIT.BY: BLUE	2012.02.03			DWG Title: Top Cover for TR9ZE1250JSTMDB2554		
DRAWN: JOHN	2012.02.03					
APPROVED: JB	2012.02.03		A.	MODEL NO: TR9ZE1250JSTMDB2554	PART NO: NA	rev. B
					SHEET 3 OF 3	

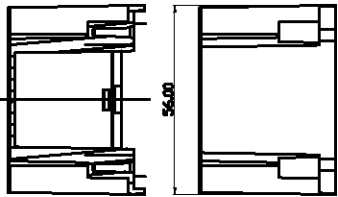
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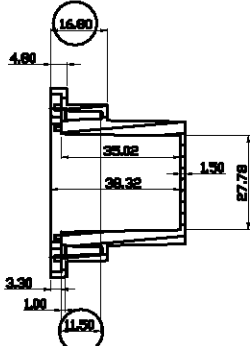
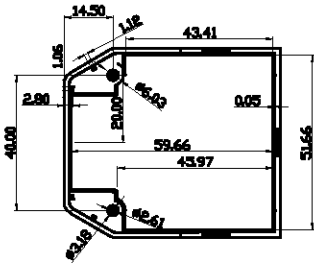
SECTION B-B

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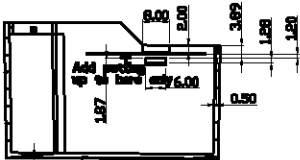
REVISION			
REV	DESCRIPTION	DATE	APPROVED
A	Initial Release	2011.10.17	JB
B	1.Add grab to secure the plastic top cover; 2. Adjust the dimension of the recess for label	2012.01.16	JB
C	Customer adjust the Enclosure: 13.50→14.50; 33.00→33.55 ;2.81→2.19and some others	2012.02.03	JB
D	Customer adjust the Enclosure: 2. 19→2.61	2012.03.02	JB
E	Customer adjust the Enclosure: 40→39.8;10→11.5;15→16.8.	2012.10.24	JB



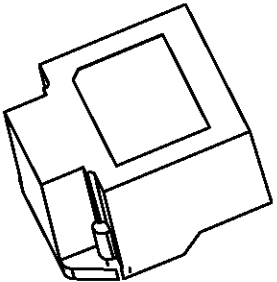
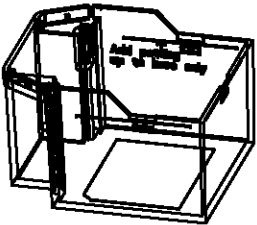
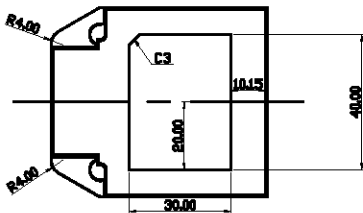
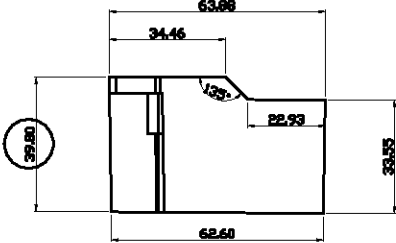
SECTION A-A



SECTION A-A



SECTION B-B



NOTED:  
Material : PC+ABS (C2950), 94V-0, BLACK, Rohs.

Tolerance table			
RANGE	GRADE 1	GRADE 2	GRADE 3
0~4	+/-0.05	+/-0.1	+/-0.2
4~16	+/-0.08	+/-0.15	+/-0.3
16~64	+/-0.12	+/-0.25	+/-0.5
64~250	+/-0.25	+/-0.4	+/-0.8

DASH NO		PART NO		REV.	DESCRIPTION		NOTES
460-01470001 (R)							
		TOLERANCES:  GRADE 1		<b>GlobTek(Suzhou), Co.,Ltd</b> Tel: +86-512-6279-0301 Fax: +86-512-6279-0355 Web: www.globtek.cn			
INIT.BY: BLUE	2012.10.24			DWG Title: Enclosure for TR9ZE1250JSTMDB2554			
DRAWN: JOHN	2012.10.24		A.	MODEL NO: TR9ZE1250JSTMDB2554	PART NO: NA	rev. E	
APPROVED: JB	2012.10.24				SHEET 2 OF 3		

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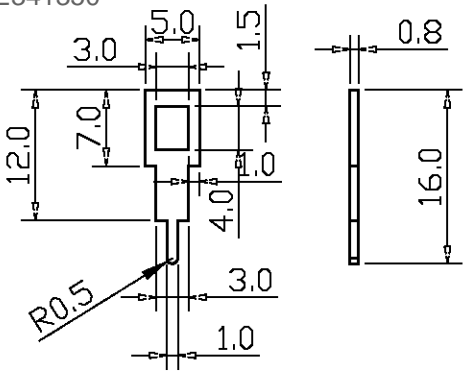
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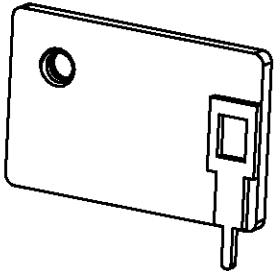
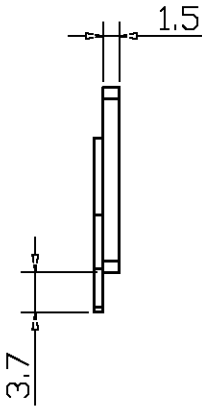
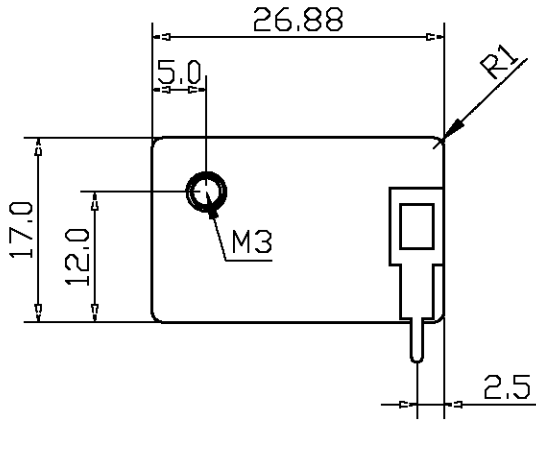


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D/A-08

REVISION 修订本			
REV	DESCRIPTION 描述	DATE	APPROVED
A	INITIAL RELEASE	11/03/11	JET

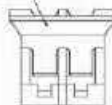
PIN: Material :tin(马口铁)



NOTE:  
1.All dimensions are in mm.  
2.Material, 1.5mm AL1050, or equivalent.  
3.It is imperative that measurements be within tolerance table for unit to function properly.

Tolerance table			
RANGE	GRADE 1	GRADE 2	GRADE 3
0~4	+/-0.05	+/-0.1	+/-0.2
4~16	+/-0.08	+/-0.15	+/-0.3
16~64	+/-0.12	+/-0.25	+/-0.5
64~250	+/-0.25	+/-0.4	+/-0.8

<p>原注:</p> <p>Globtek 公司不对未经批准而擅自修改部件而影响的安全和性能负责, 终端用户必须参考 UL、CSA 或 IEC 标准规定正确的安装。</p> <p>Foot Note:</p> <p>Globtek Inc. will not be liable for the safety and performance of these parts if unauthorized access and repair occurs. End user should consult applicable UL, CSA or IEC standards for proper installation instructions.</p>	<p>禁用:</p> <p>Globtek 产品未经授权不得使用于医疗设备中以及危险环境核试验或者飞机上, 除非有 GLOBTEK 公司首席执行官的书面正式批准。</p> <p>Limitation of Use:</p> <p>Globtek product are not authorized for use as mission critical components in life support, hazardous environment, nuclear or aircraft applications without prior written approval from the CEO of Globtek Inc.</p>	<p>文件内容未经允许不得更改</p> <p>Contents of this document are subject to change without prior notice</p>	LOCATION: 区域		PART NO 零件号		Tel: +86-512-6279-0301 Fax: +86-512-6279-0355 Web: www.globtek.cn	
			GTSZ		See table : GRADE 2		<p>Drawing Title:</p> <p>HEATSINK</p>	
			INIT. BY: 申请者	DATE: 11/03/11 日期				
			DRAWN: JOHN 制图	DATE: 11/03/11 日期	SIZE: A4	MODEL NO 型号:	PART NO 零件号:	Rev.版本
			APPROVED: 批准	DATE: 11/03/11 日期		N/A	TR9ZE1250JSTMD82554P	A
			SCALE 比例: 1:1		SHEET 1 OF 1			

**GlobTek® ,Inc.****MEDICAL POWER SUPPLY****P/N : TR9ZE1250JSTMDB2554P****MODEL : GTM41080-1812-C1****INPUT : 90-240V~,50-60Hz, 0.6A****OUTPUT : 12V 1.25A****RoHS**Circuit  
No.1**PIN 1: +12VDC**  
**PIN 2: COM**

GlobTek, Inc.

**EFFICIENCY LEVEL (V)****MADE IN CHINA (中國製造)****WWYY**

For component **without** Risk Management Process, please declare the intended use and function of your product.

Clause for IEC60601-1, 3 <sup>rd</sup> .	Intended use	Client declaration
<b>Product information</b>	Model name	GTM41080-1812-C1
	Model difference	N/A
	Input rating	90-240V~, 50-60HZ, 0.6A
	Phase	Single
	Output rating/ output loading	12Vdc, 1.25A
	Output circuits are NOT intended for direct patient connection (Type B, BF or CF)	<input checked="" type="checkbox"/> Not intended <input type="checkbox"/> Intended: _____ (circuit/output identity # _____)
	Applied Part	<input type="checkbox"/> Type B <input type="checkbox"/> Type BF <input type="checkbox"/> Type CF <input checked="" type="checkbox"/> To be determined in the end-product evaluation
	Mode of operation	<input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Duty Cycle: _____
	Maximum Operating temperature Tma	___50___ degree C
	Maximum normal load	Output was connected to resistive load as rated and operated continuously.
	Weight	_____ kg
	Dimension	64X56X40mm

	Accessories and detachable parts	<input type="checkbox"/> Part: _____ <input checked="" type="checkbox"/> To be determined in the end-product evaluation									
	Options include	<input checked="" type="checkbox"/> None <input type="checkbox"/> _____									
<b>5.7 Humidity preconditioning treatment (keep conformance to the actual test condition)</b>	Relative Humidity?	___ -- ___ %RH									
	Temperature?	___ -- ___ degree C									
	Recommend Period for Humidity preconditioning treatment?	___ -- ___ hrs (≥48hrs)									
<b>8.9 CREEPAGE DISTANCES and AIR CLEARANCES</b>	Provides MOPP or MOOP isolation?	<input type="checkbox"/> MOOP <input checked="" type="checkbox"/> MOPP									
	Altitude?	___ 5000 ___ m									
	Pollution Degree?	<input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4									
	Material group (CTI)?  <b>Table 9—Material group classification</b> <table border="1" data-bbox="595 986 1180 1228"> <thead> <tr> <th>Material group</th><th>Comparative tracking index (CTI)</th></tr> </thead> <tbody> <tr> <td>I</td><td><math>600 \leq \text{CTI}</math></td></tr> <tr> <td>II</td><td><math>400 \leq \text{CTI} &lt; 600</math></td></tr> <tr> <td>IIIa</td><td><math>175 \leq \text{CTI} &lt; 400</math></td></tr> <tr> <td>IIIb</td><td><math>100 \leq \text{CTI} &lt; 175</math></td></tr> </tbody> </table>	Material group	Comparative tracking index (CTI)	I	$600 \leq \text{CTI}$	II	$400 \leq \text{CTI} < 600$	IIIa	$175 \leq \text{CTI} < 400$	IIIb	$100 \leq \text{CTI} < 175$
Material group	Comparative tracking index (CTI)										
I	$600 \leq \text{CTI}$										
II	$400 \leq \text{CTI} < 600$										
IIIa	$175 \leq \text{CTI} < 400$										
IIIb	$100 \leq \text{CTI} < 175$										
Overvoltage category?	<input type="checkbox"/> I <input checked="" type="checkbox"/> II										

		<input type="checkbox"/> III <input type="checkbox"/> IV																									
<b>11 Protection against excessive temperatures and other HAZARDS</b>	<p>Table 23: External surfaces of ME EQUIPMENT that are likely to be touched for a time “t”</p> <p style="text-align: center;"><b>Table 23—Allowable maximum temperatures for ME EQUIPMENT parts that are likely to be touched</b></p> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th colspan="2" rowspan="2">ME EQUIPMENT and its parts</th> <th colspan="3">Maximum temperature <sup>a</sup> °C</th> </tr> <tr> <th>Metal and liquids</th> <th>Glass, porcelain, vitreous material</th> <th>Molded material, plastic, rubber, wood</th> </tr> </thead> <tbody> <tr> <td rowspan="4">External surfaces of ME EQUIPMENT that are likely to be touched for a time “t”</td> <td><math>t &lt; 1\text{ s}</math></td> <td>74</td> <td>80</td> <td>86</td> </tr> <tr> <td><math>1\text{ s} \leq t &lt; 10\text{ s}</math></td> <td>56</td> <td>66</td> <td>71</td> </tr> <tr> <td><math>10\text{ s} \leq t &lt; 1\text{ min}</math></td> <td>51</td> <td>56</td> <td>60</td> </tr> <tr> <td><math>1\text{ min} \leq t</math></td> <td>48</td> <td>48</td> <td>48</td> </tr> </tbody> </table> <p><small><sup>a</sup> These temperature limit values are applicable for touching the healthy skin of adults. They are not applicable when large areas of the skin (10 % of total body surface or more) can be in contact with a hot surface. This also applies in the case of skin contact with over 10 % of the head surface. Where this is the case, appropriate limits shall be determined and documented in the risk MANAGEMENT FILE.</small></p>	ME EQUIPMENT and its parts		Maximum temperature <sup>a</sup> °C			Metal and liquids	Glass, porcelain, vitreous material	Molded material, plastic, rubber, wood	External surfaces of ME EQUIPMENT that are likely to be touched for a time “t”	$t < 1\text{ s}$	74	80	86	$1\text{ s} \leq t < 10\text{ s}$	56	66	71	$10\text{ s} \leq t < 1\text{ min}$	51	56	60	$1\text{ min} \leq t$	48	48	48	<input checked="" type="checkbox"/> N/A <input type="checkbox"/> Parts: _____ Material: <input type="checkbox"/> Metal and liquids <input type="checkbox"/> Glass, porcelain, vitreous material <input type="checkbox"/> Molded material, plastic, rubber, wood  Touch time: <input type="checkbox"/> $t < 1\text{ s}$ <input type="checkbox"/> $1\text{ s} \leq t < 10\text{ s}$ <input type="checkbox"/> $10\text{ s} \leq t < 1\text{ min}$ <input type="checkbox"/> $1\text{ min} \leq t$
	ME EQUIPMENT and its parts			Maximum temperature <sup>a</sup> °C																							
Metal and liquids			Glass, porcelain, vitreous material	Molded material, plastic, rubber, wood																							
External surfaces of ME EQUIPMENT that are likely to be touched for a time “t”	$t < 1\text{ s}$	74	80	86																							
	$1\text{ s} \leq t < 10\text{ s}$	56	66	71																							
	$10\text{ s} \leq t < 1\text{ min}$	51	56	60																							
	$1\text{ min} \leq t$	48	48	48																							
<p>Table 24: APPLIED PART having contact with the PATIENT for a time “t”</p> <p style="text-align: center;"><b>Table 24—Allowable maximum temperatures for skin contact with ME EQUIPMENT APPLIED PARTS</b></p> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th colspan="2" rowspan="2">APPLIED PARTS OF ME EQUIPMENT</th> <th colspan="3">Maximum temperature <sup>a,b</sup> °C</th> </tr> <tr> <th>Metal and liquids</th> <th>Glass, porcelain, vitreous material</th> <th>Molded material, plastic, rubber, wood</th> </tr> </thead> <tbody> <tr> <td rowspan="3">APPLIED PART having contact with the PATIENT for a time “t”</td> <td><math>t &lt; 1\text{ min}</math></td> <td>51</td> <td>56</td> <td>60</td> </tr> <tr> <td><math>1\text{ min} \leq t &lt; 10\text{ min}</math></td> <td>48</td> <td>48</td> <td>48</td> </tr> <tr> <td><math>10\text{ min} \leq t</math></td> <td>43</td> <td>43</td> <td>43</td> </tr> </tbody> </table>	APPLIED PARTS OF ME EQUIPMENT		Maximum temperature <sup>a,b</sup> °C			Metal and liquids	Glass, porcelain, vitreous material	Molded material, plastic, rubber, wood	APPLIED PART having contact with the PATIENT for a time “t”	$t < 1\text{ min}$	51	56	60	$1\text{ min} \leq t < 10\text{ min}$	48	48	48	$10\text{ min} \leq t$	43	43	43	<input checked="" type="checkbox"/> N/A <input type="checkbox"/> Parts: _____ Material: <input type="checkbox"/> Metal and liquids <input type="checkbox"/> Glass, porcelain, vitreous material <input type="checkbox"/> Molded material, plastic, rubber, wood  Touch time: <input type="checkbox"/> $t < 1\text{ s}$ <input type="checkbox"/> $1\text{ s} \leq t < 10\text{ s}$ <input type="checkbox"/> $10\text{ s} \leq t < 1\text{ min}$ <input type="checkbox"/> $1\text{ min} \leq t$					
APPLIED PARTS OF ME EQUIPMENT			Maximum temperature <sup>a,b</sup> °C																								
		Metal and liquids	Glass, porcelain, vitreous material	Molded material, plastic, rubber, wood																							
APPLIED PART having contact with the PATIENT for a time “t”	$t < 1\text{ min}$	51	56	60																							
	$1\text{ min} \leq t < 10\text{ min}$	48	48	48																							
	$10\text{ min} \leq t$	43	43	43																							

13 HAZARDOUS SITUATIONS and fault conditions	Electrical SINGLE FAULT CONDITIONS according to 8.1	see appended test table 13
--	---	----------------------------

SIGNATURE (Authorized person): \_\_\_\_\_

lynn  
zhang

**DRAFT CB TEST CERTIFICATE INFORMATION**

Generated by ULtraLink on: 2013/06/18

Product	Medical power supply
Name and address of the Applicant	GLOBTEK (HONG KONG) LTD UNIT 1402, BENSON TOWER 74 HUNG TO RD KWUN TONG KOWLOON HONG KONG
Name and address of the Manufacturer	GLOBTEK (HONG KONG) LTD UNIT 1402, BENSON TOWER 74 HUNG TO RD KWUN TONG KOWLOON HONG KONG
Name and address of the Factory(ies)	GLOBTEK, INC. 186 VETERANS DR. NORTHVALE, NJ 07647 USA  GLOBTEK (SUZHOU) CO., LTD BUILDING 4, NO. 76, JIN LING EAST RD., SUZHOU INDUSTRIAL PARK, SUZHOU, JIANGSU 215021, CHINA
Rating and principal characteristics	Input: 90-240Vac, 50-60Hz, 0.6A Output: 12Vdc, 1.25A
Trademarks (if any)	
Model / Type ref.	GTM41080-1812-C1
Additional information (if necessary)	This report comprises _____ enclosures. This report was modified to: _____
A sample of the product was tested and found to be in conformity with	IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) See Test Report for National Differences.
As shown in the Test Report Ref. No. which forms part of this Certificate	E341350-A21

Client Representative	MS. Demon Zhou
Client email (or fax)	demon.zhou@globtek.cn

This form is to acknowledge that the above information has been reviewed and the material has been found to be accurate as stated. This is also to record client's confirmation that above factories manufacture product(s) that are equal to those submitted for testing and certification. (Refer to IECEE 02, Sub-clause 6.2.5: "When the application covers more than one factory, the address of each factory shall be stated in the CB Test Certificate and the NCB shall take steps to ensure that the products from all the factories are equal. That shall be confirmed in the Test Report.")

Signed: lyr. shang Dated: 2015. 6. 25

\*Definitions per IECEE 02 (<http://www.iecee.com/cbscheme/pdf/IECEE02.pdf>):

Applicant: A firm or a person who applies to an NCB for obtaining a CB Test Certificate.

Manufacturer: An organization, situated at a stated location or locations, that carries out or controls such stages in the manufacture, assessment, handling and storage of a product that enables it to accept responsibility for continued compliance of the product with the relevant requirements and undertakes all obligations in that connection.

Factory: The location(s) at which the product is produced or assembled and follow-up service is established by the NCB.



**Test Record No. 1**

The manufacturer submitted representative production samples of Medical Power Supply, models GTM41080-1812-C1.

Test results are valid only for the tested equipment. These tests are considered representative of the products covered by this Test Report. The test methods and results of the above tests have been reviewed and found to be in accordance with the requirements in the Standard(s) referenced at the beginning of this Test Report.

The results of this investigation, including construction review and testing, indicate that the products evaluated comply with the applicable requirements in the standard for IEC 60601-1: 2005 + CORR.1 (2006) + CORR.2 (2007) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) - Edition 3, ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) - Edition 1 - Revision Date 2012/01/01, CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) Edition 2 - Revision Date 2011/06/01

Any information and documentation involving UL Mark services are provided on behalf of UL LLC (UL) or any authorized licensee of UL.

The following tests were conducted:

Test	Testing Location/Comments
Power Input Test (4.11)	Underwriters Laboratories Taiwan Co., Ltd./4th & 5th Fl., No. 35, Sec. 2, ChungYang S. Road, Peitou, Taipei City 112, Taiwan ,This test is performed at 80V input voltage instead of 81V as customer required.
Humidity Preconditioning Treatment (5.7)	Underwriters Laboratories Taiwan Co., Ltd./4th & 5th Fl., No. 35, Sec. 2, ChungYang S. Road, Peitou, Taipei City 112, Taiwan
Durability of Marking Test (7.1.3)	Underwriters Laboratories Taiwan Co., Ltd./4th & 5th Fl., No. 35, Sec. 2, ChungYang S. Road, Peitou, Taipei City 112, Taiwan
Low Voltage Reliability (8.4.2 and 8.11.1)	Underwriters Laboratories Taiwan Co., Ltd./4th & 5th Fl., No. 35, Sec. 2, ChungYang S. Road, Peitou, Taipei City 112, Taiwan
Voltage or Charge Limitation (8.4.3)	Underwriters Laboratories Taiwan Co., Ltd./4th & 5th Fl., No. 35, Sec. 2, ChungYang S. Road, Peitou, Taipei City 112, Taiwan
Working Voltage Measurement (8.5.4)	Underwriters Laboratories Taiwan Co., Ltd./4th & 5th Fl., No. 35, Sec. 2, ChungYang S. Road, Peitou, Taipei City 112, Taiwan
Dielectric Voltage Withstand (8.8.3)	Underwriters Laboratories Taiwan Co., Ltd./4th & 5th Fl., No. 35, Sec. 2, ChungYang S. Road, Peitou, Taipei City 112, Taiwan
Ball Pressure (8.8.4.1)	Underwriters Laboratories Taiwan Co., Ltd./4th & 5th Fl., No. 35, Sec. 2, ChungYang S. Road, Peitou, Taipei City 112, Taiwan
Temperature Test (11)	Underwriters Laboratories Taiwan Co., Ltd./4th & 5th Fl., No. 35, Sec. 2, ChungYang S. Road, Peitou, Taipei City 112, Taiwan / This test is performed at 80V input voltage instead of 81V as customer required.
Interruption of Power Supply (11.8)	Underwriters Laboratories Taiwan Co., Ltd./4th & 5th Fl., No. 35, Sec. 2, ChungYang S. Road, Peitou, Taipei City 112, Taiwan

Abnormal Operation and Single Fault Conditions (13)	Underwriters Laboratories Taiwan Co., Ltd./4th & 5th Fl., No. 35, Sec. 2, ChungYang S. Road, Peitou, Taipei City 112, Taiwan
Power Availability (13.1.2)	Underwriters Laboratories Taiwan Co., Ltd./4th & 5th Fl., No. 35, Sec. 2, ChungYang S. Road, Peitou, Taipei City 112, Taiwan
Enclosure Mechanical Strength (15.3)	Underwriters Laboratories Taiwan Co., Ltd./4th & 5th Fl., No. 35, Sec. 2, ChungYang S. Road, Peitou, Taipei City 112, Taiwan
Drop Test (15.3.4)	Underwriters Laboratories Taiwan Co., Ltd./4th & 5th Fl., No. 35, Sec. 2, ChungYang S. Road, Peitou, Taipei City 112, Taiwan
Mold Stress Relief Test (15.3.6)	Underwriters Laboratories Taiwan Co., Ltd./4th & 5th Fl., No. 35, Sec. 2, ChungYang S. Road, Peitou, Taipei City 112, Taiwan
Transformer Overload and Short-Circuit Tests (15.5.1)	Underwriters Laboratories Taiwan Co., Ltd./4th & 5th Fl., No. 35, Sec. 2, ChungYang S. Road, Peitou, Taipei City 112, Taiwan
Leakage Current Test (8.7)	Underwriters Laboratories Taiwan Co., Ltd./4th & 5th Fl., No. 35, Sec. 2, ChungYang S. Road, Peitou, Taipei City 112, Taiwan

Test results are valid only for the tested equipment. These tests are considered representative of the products covered by this Test Report. The test methods and results of the above tests have been reviewed and found to be in accordance with the requirements in the Standard(s) referenced at the beginning of this Test Report.

The following supplements are provided as a part of this Test Record. NOTE: These supplements are only available to the Applicant via the CDA system.

<u>Type</u>	<u>Supplement Id</u>	<u>Description</u>
Attachment	2-01	CRD
Datasheet	2-02	Datasheet
Insulation Diagram	10-01	Insulation Diagram
Insulation Table	10-02	Insulation Table

**Test Record No. 2**

The manufacturer submitted representative production samples of Medical Power Supply, models GTM41080-1812-C1.

No test was considered necessary due to similarity of previous project investigation except adding the alternate AC inlet, Model 6102-91 by SCHURTER (E96454) and IP rating 67 ( IP 67 report was provided by customer and include adding AC power cord), see report E341350-A21, test record 1

The results of this investigation, including construction review and testing, indicate that the products evaluated comply with the applicable requirements in the standard for IEC 60601-1: 2005 + CORR.1 (2006) + CORR.2 (2007) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) - Edition 3, ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) - Edition 1 - Revision Date 2012/01/01, CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) Edition 2 - Revision Date 2011/06/01

Any information and documentation involving UL Mark services are provided on behalf of UL LLC (UL) or any authorized licensee of UL.

The following supplements are provided as a part of this Test Record. NOTE: These supplements are only available to the Applicant via the CDA system.

<u>Type</u>	<u>Supplement Id</u>	<u>Description</u>
Attachment	2-03	CRD

Project: 13CA03570File: E341350

Page 1 of 2

Compliance Review  
Conducted by:

Sammi Liang/ Annie Niu

May, 20<sup>th</sup>, 2013

Printed Name

Signature

Date

**CONSTRUCTION COMPLIANCE REVIEW RECORD****SAMPLE IDENTIFICATION:**

Sample Card #	Date Received	Sample #	Manufacturer, Product Identification and Ratings
1556445	01-29-2013	--	Glob tek, Medical Power Supply, type GTM41080-1812-C1 (UNSEALED)*5 Rated Input: 90-240Vac 50-50Hz, 0.6A Output: 12Vdc, 1.25A
1556445	01-29-2013	--	Glob tek, Medical Power Supply, type GTM41080-1812-C1 (SEALED)*3 Rated Input: 90-240Vac 50-50Hz, 0.6A Output: 12Vdc, 1.25A
1556445	01-29-2013	--	Shan Dong BOAM /Glob Tek /Wuxi Zhong tong Type XF00579A Transformer*2
1556445	01-29-2013	--	Label*7 Type XQ03 and XQ004-B (Dong Guan Xian quan), FJ-03-3 and FJ07 (Fan JA Paper), EL-15 ( E-Lin Adhesive ), CW-01(SHENZHEN CORWIN ), JL-08 (YUEN CHANG )
1556445	01-29-2013	--	Fuse*15 Type: MST (Conquer) Rating : T1.6A/250Vac
1556445	01-29-2013	--	Insulation Wire*3 Type TEX-E (Furukawa ) , TRW(B) (Great Leoflon) and TIW-M (Cosmolink)
1556445	01-29-2013	--	Insulation Tape*2 Type PZ (YAHUA) and JY25-A (JINGJIANG JINGYI )

The alternation is not related to insulation, therefore no insulation measurement was conducted.

**MEASUREMENT INSTRUMENT INFORMATION:** (Ex. Micrometer, Calipers, Comparator)

Inst. ID #	Instrument Type	Function/Range	Last Cal. Date	Next Cal. Date
SUB-LT-CA137	Caliper	0-150mm	2013-03-21	2014-03-20

The following additional information is required when using client's or rented equipment, or when a UL ID Number for an instrument number is not used. The Inst. ID # below corresponds to the Inst. ID # above.

Inst. ID #	Make / Model / Serial Number / Asset No.

**CONSTRUCTION COMPLIANCE REVIEW:**

The sample was reviewed for compliance with the construction requirements in the standard(s) indicated below and a complete record including measurements to support compliance with those requirements is detailed in Report Reference Number E341350-A21

Standard(s):

- ☐ CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) Edition 2 - Revision Date 2011/06/01
- ☐ ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) - Edition 1 - Revision Date 2012/01/01
- ☒ ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) - Edition 1 - Revision Date 2012/01/01, CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) Edition 2 - Revision Date 2011/06/01, IEC 60601-1: 2005 + CORR.1 (2006) + CORR.2 (2007) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) - Edition 3

Project No. 4786338356

File E341350

Page 1

Compliance

Review

Conducted by: Jeffery ChanJeffery ChanDate 2014-03-21

Printed Name

Signature

## CONSTRUCTION COMPLIANCE REVIEW RECORD

## Sample Identification -

Sample Card No.	Date Received	Sample No.	Manufacturer, Product Identification and Ratings
1837704	2014-03-18	1	GLOBTEK (HONG KONG) LTD, MODEL: GTM41080-1812-C1 Input: 90-240Vac, 50-60Hz, 0.6A Output: 12Vdc, 1.25A

## Measurement Instrument Information -

Inst. ID No.	Instrument Type	Function/Range	Last Cal. Date	Next Cal. Date
DC003	Digital Caliper	0-150 mm	2013-04-25	2014-04-25

The following additional information is required when using client's or rented equipment, or when a UL ID Number for an instrument number is not used. The Inst. ID No. below corresponds to the Inst. ID No. above.

Inst. ID No.	Make/Model/Serial Number/Asset No.
--	--

[ X ] Measurement instrument information is recorded on UL's Laboratory Project Management (LPM) database. (This statement may be selected only if CRDs are completed at a UL facility)

Project No. 4786338356 File E341350 Page 2  
Compliance  
Review  
Conducted by: Jeffery Chan Jeffery Chan Date 2014-03-21  
Printed Name Signature

## CONSTRUCTION COMPLIANCE REVIEW:

The sample was reviewed for compliance with the construction requirements in the standard indicated below and a complete record including measurements to support compliance with those requirements is detailed in Report Reference No. E341350-A21.

## Standard(s):

CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) Edition 2 - Revision Date 2011/06/01

ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) - Edition 1 - Revision Date 2012/01/01

IEC 60601-1: 2005 + CORR.1 (2006) + CORR.2 (2007) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) - Edition 3