




## RECOGNIZED COMPONENT Constructional Data Report (CDR)

| 1.0 Reference and Address |   |                  |  |
|---------------------------|---|------------------|--|
| Report Number             | 150702593SHA-001  | Original Issued: | 14-Aug-2015  |
|                           |   | Revised:         | None   |
| Standard(s)               | ANSI/AAMI ES60601-1; A1 Issued: 2006/03/09: 2005 Version Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance; with AMD 1; 2012/11/08 & 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.   |
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| 2.0 Product Description |  |
|-------------------------|--|
| Product                 | Medical Power Supply   |
| Brand name              |   |
| 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 two structure types respectively. One is power adapter model, which can be used with detachable power supply cord. Different appliance inlets can be interchangeable on the device, which can provide with earthing connection or not. Protective earthing connection to secondary circuit by internal wiring is optional, so it can be Class I or Class II construction. Both two constructions are in consideration in this report. Two pieces of outer enclosure are enclosed with screws.</p> <p>The other one is open frame power supply board which also provides a protective earth bonding terminal on the PCB board. The installation and use for the insulation construction shall be finally determined in the end product.</p> <p>Models GTM43004P-12016-4.0-T3, GTM43004P-508.9-3.9-T3 and GTM43004P-12048-12.0-T3 are tested as typical models. Model GTM43004P-12024-T2 has two structures, one is same as the other series models, the different has a surge arrester VT1 and use a bigger varistor for 4kV surge test of EMC.</p> <p>Different transformer types are alternative, which are identical in same construction except different routing of secondary lead wires and shield foil.</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.</p> |
| Models                  | GT*43004P-***-**   |
| Model Similarity        | <p>GT*43004P-***-**</p> <p>The 1st “*” part can be ‘M’ or ‘-’ or ‘H’ for market identification and not related to safety.</p> <p>The 2nd “*” part denotes the rated output wattage designation, which can be “01” to “120”, with interval of 1, two digitals for 01-99W, three digitals for 100-120W.</p> <p>The 3rd “*” part denotes the standard rated output voltage designation, which can be “8.9”, “16”, “24”, “35” and “48”.</p> <p>The 4th “*” part is optional, which can be “-0.1” to “-12.9” with interval of 0.1 to denote voltage deviation or blank to indicate no voltage different. The result by subtracting the deviation value from the standard rated output voltage denotes the rated output voltage, with a range of 5-48 volts.</p> <p>The 5th “*” part can be ‘F’ to denote open frame power supply model or ‘T’ to denote power adapter model. The 6th “*” part can be ‘2’ to denote Class II model, or ‘3’ or ‘3A’ to denote two types of Class I models with different appliance inlets when the 5th “*” part is ‘T’. Otherwise, the 6th “*” part is blank when the 5th “*” part is ‘F’.</p>  |
| Ratings                 | <p>Input: 100-240V~, 50-60Hz, 2.0A;</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>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"><li>• Clause 7.5 (Safety Signs),</li><li>• 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.),</li><li>• Clause 8.11.5 (Mains Fuse with High Breaking Capacity),</li><li>• Clause 9 (ME Hazard), except 9.1 and 9.3 are evaluated,</li><li>• Clause 10 (Radiation),</li><li>• Clause 11.7 (Biocompatibility),</li><li>• Clause 14 (PEMS),</li><li>• Clause 16 (ME Systems)</li><li>• Clause 17 (EMC),</li></ul> |

| 4.0 Critical Components |                       |                   |   |                           |   |                                    |
|-------------------------|-----------------------|-------------------|---|---------------------------|---|------------------------------------|
| Photo #                 | Item no. <sup>1</sup> | Name              | Manufacturer/ trademark <sup>2</sup>          | Type / model <sup>2</sup> | Technical data and securement means                         | Mark(s) of conformity <sup>3</sup> |
| 1                       | 1                     | Plastic enclosure | SABIC INNOVATIVE PLASTICS B V                 | SE1X                      | Min. V-1 at 1.5 mm thickness, 105 °C                        | cURus                              |
|                         |                       |                   | SABIC INNOVATIVE PLASTICS B V                 | C2950                     | Min. V-0 at 1.5 mm thickness, 75° C                         |                                    |
|                         |                       |                   | SABIC INNOVATIVE PLASTICS B V                 | CX7211 EXCY0098           | Min. V-1 at 1.25 mm thickness, 85 °C                        |                                    |
|                         |                       |                   | TEIJIN CHEMICALS LTD                          | LN-1250P LN-1250G         | Min. V-0 at 1.5 mm thickness, 115 °C                        |                                    |
|                         |                       |                   | CHI MEI Corporation                           | PA-765A                   | Min. V-1 at 1.5 mm thickness, 80° C                         |                                    |
|                         |                       |                   | CHI MEI Corporation                           | PC-540                    | Min. V-0 at 1.5 mm thickness, 70° C                         |                                    |
| 2                       | 2                     | Label             | DONGGUAN XIANGQUAN PRINTING CO LTD            | XQ03                      | Rated min 80°C<br>Suitable for use on the plastic enclosure | cURus                              |
|                         |                       |                   | FAN JA PAPER PRINTING CO LTD                  | FJ-03-3                   |   |                                    |
|                         |                       |                   | FAN JA PAPER PRINTING CO LTD                  | FJ07                      |   |                                    |
|                         |                       |                   | DONGGUAN XIANGQUAN PRINTING CO LTD            | XQ004-B                   |   |                                    |
|                         |                       |                   | E-LIN ADHESIVE LABEL CO LTD                   | EL-15                     |   |                                    |
|                         |                       |                   | SHENZHEN CORWIN PRINTING CO LTD               | CW-01                     |   |                                    |
|                         |                       |                   | YUEN CHANG SPECIAL PRINTING (SHENZHEN) CO LTD | JL-08<br>JL-02            |   |                                    |
|                         |                       |                   | Various                                       | Various                   |   |                                    |
|                         |                       |                   | GlobTek                                       | Various                   | Engraving or Silkscreen (Optional)                          | NR                                 |
| 3                       | 3                     | Output cord       | Various                                       | Various                   | Min. 24AWG, min. 300V, min. 80° C                           | cURus                              |

| 4.0 Critical Components |                       |  |   |                           |  |                                    |
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| 3                       | 4                     | Appliance inlet (only for power adapter model) | Zhejiang LECI Electronics Co., Ltd.         | DB-6                      | 2.5A, 250Vac, for Class I model<br>Standard sheet: C6  | cURus                              |
|                         |                       |  | Rich Bay Co., Ltd.                          | R-30790                   |  |                                    |
|                         |                       |  | Sun Fair Electric Wire & Cable (HK)Co. Ltd. | S-02                      |  |                                    |
|                         |                       |  | TECX-UNIONS Technology Corporation          | TU-333 series             |  |                                    |
|                         |                       |  | Rong Feng Industrial Co., Ltd.              | RF-190                    |  |                                    |
|                         |                       |  | Inalways Corporation                        | 0724                      |  |                                    |
|                         |                       |  | Zhejiang LECI Electronics Co., Ltd.         | DB-14                     | 10A, 250Vac, for Class I model<br>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<br>TU-301-SP     |  |                                    |
|                         |                       |  | Rong Feng Industrial Co., Ltd.              | SS-120                    |  |                                    |
|                         |                       |  | Inalways Corporation                        | 0711 series               |  |                                    |
|                         |                       |  | Zhejiang LECI Electronics Co., Ltd.         | DB-8                      | 2.5A, 250Vac, for Class II model<br>Standard sheet: C8 |                                    |
|                         |                       |  | 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               |  |                                    |

| 4.0 Critical Components |                       |                             |  |   |  |                                    |
|-------------------------|-----------------------|-----------------------------|--|---|--|------------------------------------|
| Photo #                 | Item no. <sup>1</sup> | Name                        | Manufacturer/ trademark <sup>2</sup>                                     | Type / model <sup>2</sup>   | Technical data and securement means  | Mark(s) of conformity <sup>3</sup> |
| 4                       | 5                     | Insulating sheet            | FORMEX,DIV OF IL TOOL WORKS INC, FRMRLY FASTEX, DIV OF IL TOOL WORKS INC | FORMEX GK series  | V-0, min. 0.4 mm thickness, min. 115°C   | cURus                              |
|                         |                       |                             | SKC CO LTD   | SH71S   | VTM-2, min. 0.4 mm thickness, min. 105°C                                       |                                    |
|                         |                       |                             | TORAY INDUSTRIES INC   | Lumirror H10  | VTM-2, min. 0.4 mm thickness, min. 105°C                                       |                                    |
|                         |                       |                             | SABIC INNOVATIVE PLASTICS US L L C                                       | FR60 series<br>FR63 series<br>FR65 series<br>FR7 series<br>FR700 series | V-0, min. 0.4 mm thickness, min. 130°C   |                                    |
|                         |                       |                             | MIANYANG LONGHUA FILM CO LTD   | PP-BK-20<br>PP-BK-17<br>PP-BK-18  | VTM-0, min. 0.4 mm thickness, min. 80°C  |                                    |
|                         |                       |                             | ITW ELECTRONICS COMPONENTS/ PRODUCTS (SHANGHAI) CO LTD                   | FORMEX-18<br>FORMEX-17  | V-0, min. 0.4 mm thickness, min. 100°C   |                                    |
| 6                       | 6                     | Fuse (FS1, FS2)             | Conquer Electronics Co., Ltd.  | MST   | T4A, 250V, Rated breaking capacity 100A<br>FS2 is optional in Class II product | cURus                              |
|                         |                       |                             | Ever Island Electric Co., Ltd. and Walter Electric                       | 2010  | T4A, 250V, Rated breaking capacity 130A<br>FS2 is optional in Class II product |                                    |
|                         |                       |                             | Bel Fuse Ltd.  | RST   | T4A, 250V, Rated breaking capacity 100A<br>FS2 is optional in Class II product |                                    |
|                         |                       |                             | Cooper Bussmann LLC  | SS-5  | T4A, 250V, Rated breaking capacity 35A<br>FS2 is optional in Class II product  |                                    |
|                         |                       |                             | Walter Electronic Co. Ltd.   | ICP series  | T4A, 250V, Rated breaking capacity 50A<br>FS2 is optional in Class II product  |                                    |
|                         |                       |                             | Das & Sons International Ltd.  | 385T series   | T4A, 250V, Rated breaking capacity 35A<br>FS2 is optional in Class II product  |                                    |
| 6                       | 7                     | Choke coil (LF1) (Optional) | GlobTek BOAM ZhongTong   | RC00088   | Class A  | NR                                 |
|                         |                       |                             |  |   |  |                                    |

| 4.0 Critical Components |                       |                             |  |  |                                     |                                    |
|-------------------------|-----------------------|-----------------------------|--|--|-------------------------------------|------------------------------------|
| Photo #                 | Item no. <sup>1</sup> | Name                        | Manufacturer/ trademark <sup>2</sup>           | Type / model <sup>2</sup>                | Technical data and securement means | Mark(s) of conformity <sup>3</sup> |
| 6                       | 8                     | Varistor (MOV1) (optional)  | JOYIN CO LTD                                   | 07N471K<br>10N471K<br>14N471K            | Maximum continuous voltage: 300V    | cURus                              |
|                         |                       |                             | CENTRA SCIENCE CORP                            | 07D471K<br>10D471K<br>14D471K            |                                     |                                    |
|                         |                       |                             | THINKING ELECTRONIC INDUSTRIAL CO LTD          | TVR07471K<br>TVR10471K<br>TVR14471K      |                                     |                                    |
|                         |                       |                             | SUCCESS ELECTRONICS CO LTD                     | SVR07D471K<br>SVR10D471K<br>SVR14D471K   |                                     |                                    |
|                         |                       |                             | CERAMATE TECHNICAL CO LTD                      | GNR07D471K<br>GNR10D471K<br>GND14D471K   |                                     |                                    |
|                         |                       |                             | BRIGHTKING (SHENZHEN) CO LTD                   | 07D471K<br>10D471K<br>14D471K            |                                     |                                    |
|                         |                       |                             | LIEN SHUN ELECTRONICS CO LTD                   | 07D471K<br>10D471K<br>14D471K            |                                     |                                    |
|                         |                       |                             | HONGZHI ENTERPRISES LTD                        | HEL-7D471K<br>HEL-10D471K<br>HEL-14D471K |                                     |                                    |
|                         |                       |                             | GUANGXI NEW FUTURE INFORMATION INDUSTRY CO LTD | 07D471K<br>10D471K<br>14D471K            |                                     |                                    |
| 6                       | 9                     | Choke coil (LF2) (Optional) | GlobTek<br>ZhongTong<br>BOAM                   | RC00150                                  | Class A                             | NR                                 |
| 6                       | 10                    | Choke coil (L1) (Optional)  | GlobTek<br>ZhongTong<br>BOAM                   | RC00085                                  | Class A                             | NR                                 |
| 6                       | 11                    | PFC Choke (L2)              | GlobTek<br>BOAM<br>ZhongTong<br>HEJIA          | XF00730                                  | Class A                             | NR                                 |

| 4.0 Critical Components |                       |  |  |   |  |                                    |
|-------------------------|-----------------------|--|--|---|--|------------------------------------|
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| 6                       | 12                    | X capacitor (CX1) (optional)             | Cheng Tung Industrial Co., Ltd.                | CTX                                       | Max.0.47uF, 310V, 110°C, type X1 or X2 | cURus                              |
|                         |                       |  | Tenta Electric Industrial Co. Ltd.             | MEX                                       | Max.0.47uF, 250V, 110°C, type X2       |                                    |
|                         |                       |  | Ultra Tech Xiphi Enterprise Co. Ltd.           | HQX                                       | Max.0.47uF, 275V, 100°C, type X2       |                                    |
|                         |                       |  | Okaya Electric Industries                      | RE series                                 | Max.0.47uF, 250V, 110°C, type X2       |                                    |
|                         |                       |  | VISHAY Capacitors Belgium NV                   | F1772                                     | Max.0.47uF, 310V, 110°C, type X1 or X2 |                                    |
|                         |                       |  | Winday Electronic Industries Co., Ltd.         | MPX                                       | Max.0.47uF, 310V, 110°C, type X2       |                                    |
|                         |                       |  | Dain Electronics Co., Ltd.                     | MPX, MEX and NPX                          | Max.0.47uF, 250V, 110°C, type X2       |                                    |
|                         |                       |  | Sinhua Electronics (Huzhou) Co., Ltd.          | MPX                                       | Max.0.47uF, 300V, 110°C, type X2       |                                    |
|                         |                       |  | Shunde Da Hua Electric Co., Ltd.               | HD-MKP                                    | Max.0.47uF, 250V, 105°C, type X2       |                                    |
|                         |                       |  | Foshan Shunde Chuang Ge                        | MKP-X2                                    | Max.0.47uF, 275V, 105°C, type X2       |                                    |
|                         |                       |  | Hongzhi Enterprises Ltd.                       | MPX                                       | Max.0.47uF, 250V, 100°C, type X2       |                                    |
|                         |                       |  | Jiangsu Xinghua Huayu Co., Ltd.                | MPX                                       | Max.0.47uF, 250V, 100°C, type X2       |                                    |
| 6                       | 13                    | Insulating tape wrapped around heat-sink | 3M COMPANY ELECTRICAL MARKETS DIV (EMD)        | 1350F series<br>1350T series<br>44 series | Min.130°C                              | cURus                              |
|                         |                       |  | BONDTEC PACIFIC CO LTD                         | 370S                                      |  |                                    |
|                         |                       |  | JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CO LTD | PZ series<br>CT series                    |  |                                    |
|                         |                       |  | JINGJIANG JINGYI ADHESIVE PRODUCT CO LTD       | JY25-A                                    |  |                                    |
|                         |                       |  | CHANG SHU LIANG YI TAPE INDUSTRY CO LTD        | LY-XX                                     |  |                                    |



| 4.0 Critical Components |                       |  |   |                                      |   |                                    |
|-------------------------|-----------------------|--|---|--------------------------------------|---|------------------------------------|
| Photo #                 | Item no. <sup>1</sup> | Name   | Manufacturer/ trademark <sup>2</sup>          | Type / model <sup>2</sup>            | Technical data and securement means         | Mark(s) of conformity <sup>3</sup> |
| 6                       | 14                    | Insulating tube (Used on appliance inlet pin-out or wrapped around heatsink) | SHENZHEN WOER HEAT-SHRINKABLE MATERIAL CO LTD | RSFR<br>RSFR-H<br>RSFR-HPF           | 600V, 125°C                                 | cURus                              |
|                         |                       |  | QIFURUI ELECTRONICS CO                        | QFR-h                                | 600V, 125°C                                 |                                    |
|                         |                       |  | DONGGUAN SALIPT CO LTD                        | SALIPT S-901-300<br>SALIPT S-901-600 | Min. 300V, 125°C                            |                                    |
|                         |                       |  | GUANGZHOU KAIHENG ENTERPRISE GROUP            | K-2 (+)<br>K-2 (CB)                  | Min. 300V, 125°C                            |                                    |
|                         |                       |  | CHANGYUAN ELECTRONICS (SHENZHEN) CO LTD       | CB-HFT                               | Min. 300V, 125°C                            |                                    |
| 6                       | 15                    | Y-Capacitor (CY1, CY2) (optional)  | TDK-EPC CORPORATION                           | CD                                   | Type Y1, max. 2200pF, min. 250V, min. 125°C | cURus                              |
|                         |                       |  | SUCCESS ELECTRONICS CO LTD                    | SE<br>SB                             |   |                                    |
|                         |                       |  | MURATA MFG CO LTD                             | KX                                   |   |                                    |
|                         |                       |  | WALSIN TECHNOLOGY CORP                        | AH                                   |   |                                    |
|                         |                       |  | JYA-NAY CO LTD                                | JN                                   |   |                                    |
|                         |                       |  | HAOHUA ELECTRONIC CO                          | CT7                                  |   |                                    |
|                         |                       |  | HONGZHI ENTERPRISES LTD                       | Y                                    |   |                                    |
|                         |                       |  | JERRO ELECTRONICS CORP                        | JX-series                            |   |                                    |
| 6                       | 16                    | Transformer (T1)   |   | XF00828                              | Class B                                     | NR                                 |
|                         |                       |  | GlobTek                                       | XF00870                              |   |                                    |
|                         |                       |  | BOAM  | XF00849                              |   |                                    |
|                         |                       |  | HAOPUWEI                                      | XF00854                              |   |                                    |
|                         |                       |  | HEJIA   | XF00830                              |   |                                    |
| -                       | 17                    | Triple-insulated wire (Secondary) (not shown)                                | GREAT LEOFLON INDUSTRIAL CO LTD               | TRW(B)                               | Min.130°C                                   | cURus                              |
|                         |                       |  | COSMOLINK CO LTD                              | TIW-M                                |   |                                    |
|                         |                       |  | FURUKAWA ELECTRIC CO LTD                      | TEX-E                                |   |                                    |
|                         |                       |  | CHANGYUAN ELECTRONICS (SHENZHEN) CO LTD       | CB-TIW                               |   |                                    |
|                         |                       |  | SHENZHEN JIUDING NEW MATERIAL CO LTD          | DTIW-B                               |   |                                    |

| 4.0 Critical Components |                       |                                 |  |                           |                                     |                                    |
|-------------------------|-----------------------|---------------------------------|--|---------------------------|-------------------------------------|------------------------------------|
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| -                       | 18                    | Bobbin (not shown)              | CHANG CHUN PLASTICS CO LTD                             | T375J<br>T375HF           | V-0, 150°C, thickness 0.45 mm min.  | cURus                              |
|                         |                       |                                 | SUMITOMO BAKELITE CO LTD                               | PM-9820                   |                                     |                                    |
|                         |                       |                                 | HITACHI CHEMICAL CO LTD                                | CP-J-8800                 |                                     |                                    |
| 20                      | 19                    | Insulating tape                 | 3M COMPANY ELECTRICAL MARKETS DIV (EMD)                | 1350F-1<br>1350T-1<br>44  | Min.130°C                           | cURus                              |
|                         |                       |                                 | BONDTEC PACIFIC CO LTD                                 | 370S                      |                                     |                                    |
|                         |                       |                                 | JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CO LTD         | PZ CT                     |                                     |                                    |
|                         |                       |                                 | JINGJIANG JINGYI ADHESIVE PRODUCT CO LTD               | JY25-A                    |                                     |                                    |
|                         |                       |                                 | CHANG SHU LIANG YI TAPE INDUSTRY CO LTD                | LY-XX                     |                                     |                                    |
| 6                       | 20                    | Earthing wire for Class I model | KUNSHAN NEW ZHICHENG ELECTRONICS TECHNOLOGIES CO LTD   | 1015<br>1007              | Min. 20 AWG, Min. 300V, Min. 80° C  | cURus                              |
|                         |                       |                                 | ZHUANG SHAN CHUAN ELECTRICAL PRODUCTS (KUNSHAN) CO LTD |                           |                                     |                                    |
|                         |                       |                                 | DONGGUAN CHUANTAI WIRE PRODUCTS CO LTD                 |                           |                                     |                                    |
|                         |                       |                                 | YONG HAO ELECTRICAL INDUSTRY CO LTD                    |                           |                                     |                                    |
|                         |                       |                                 | DONGGUAN GUNEETAL WIRE & CABLE CO LTD                  |                           |                                     |                                    |
|                         |                       |                                 | SHENG YU ENTERPRISE CO LTD                             |                           |                                     |                                    |
|                         |                       |                                 | Various  |                           |                                     |                                    |

| 4.0 Critical Components |                       |                              |   |                           |  |                                    |
|-------------------------|-----------------------|------------------------------|---|---------------------------|--|------------------------------------|
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| 7                       | 21                    | PCB material                 | TECHNI TECHNOLOGY LTD                     | T2A<br>T2B<br>T4          | Min 1.6 mm thickness, min. V-0, 130°C                            | cURus                              |
|                         |                       |                              | DONGGUAN HE TONG ELECTRONICS CO LTD       | CEM1                      |  |                                    |
|                         |                       |                              | CHEERFUL ELECTRONIC                       | 03<br>03A                 |  |                                    |
|                         |                       |                              | DONGGUAN DAYSUN ELECTRONIC CO LTD         | DS2                       |  |                                    |
|                         |                       |                              | SUZHOU CITY YILIHUA ELECTRONICS CO LTD    | YLH-1                     |  |                                    |
|                         |                       |                              | SHANGHAI AREX PRECISION ELECTRONIC CO LTD | 02V0<br>04V0              |  |                                    |
|                         |                       |                              | BRITE PLUS ELECTRONICS (SUZHOU) CO LTD    | DKV0-3A                   |  |                                    |
|                         |                       |                              | GOLDEN TRIANGLE PCB & TECHNOLOGIES LTD    | GT-D                      |  |                                    |
|                         |                       |                              | SHENZHEN TONGCHUANGXIN ELECTRONICS CO LTD | TCX                       |  |                                    |
|                         |                       |                              | Various                                   | Various                   |  |                                    |
| 11                      | 22                    | Optocoupler (U2)             | LITE-ON Technology Corporation            | LTV-817C                  | 2MOPP at working voltage 250Vrms, 100°C<br>With CB certification | NR                                 |
|                         |                       |                              | Everlight Electronics Co., Ltd.           | EL817                     |  |                                    |
| -                       | 23                    | Insulation system(not shown) | GlobTek, Inc                              | GTX-130-TM                | Class B  | cURus                              |
|                         |                       |                              | BOAM                                      | BOAM-01                   |  |                                    |
|                         |                       |                              |   | 130-1                     |  |                                    |
|                         |                       |                              | WUXI HAOPUWEI ELECTRONICS CO LTD          | ZT-130                    |  |                                    |
|                         |                       |                              | HEJIA                                     | HJ130(B)                  |  |                                    |

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.

|   |
|---|
| <b>5.0 Critical Unlisted CEC Components</b> |
|---|

|  |
|--|
| <b>No Unlisted CEC components are used in this report.</b> |
|--|

## 6.0 Critical Features

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

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

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

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

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

1. Spacing - Refer to illustration No(s) 2 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 3 and 4.
5. Grounding - This product is not provided with a means of grounding as it is double insulated for Class II model. The accessible contacts of secondary terminal (-) are connected to the equipment grounding terminal for Class I model. Final determination in end product evaluation for open frame model.
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 wiring is minimum 24 AWG, with a minimum rating of 300V, 80°C.
8. Schematics - Refer to Illustration No(s). 3-4 for schematics & PCB layout requiring verification during Field Representative Inspection Audits.
9. Markings - The product is marked as follows: brand name, model number, electrical ratings, manufacturer. Refer to Illustration No. 6 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.

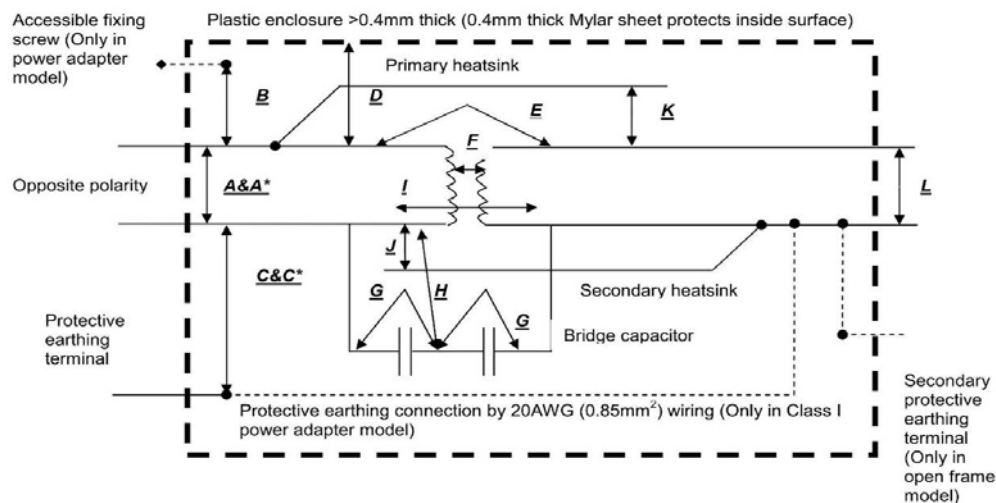
## 7.0 Illustrations

### Illustration 1 - Model list

| Model              | Rated output<br>voltage range | Max. rated output<br>current | Max. rated output<br>power | Transformer model |
|--------------------|-------------------------------|------------------------------|----------------------------|-------------------|
| GT*43004P-*8.9*-** | 5-8.9Vdc                      | 10A                          | 90W                        | XF00828           |
| GT*43004P-*16*-**  | 9-16Vdc                       | 10A                          | 90W                        | XF00870           |
| GT*43004P-*24*-**  | 16.1-24Vdc                    | 7.45A                        | 120W                       | XF00849           |
| GT*43004P-*35*-**  | 24.1-35Vdc                    | 5A                           | 120W                       | XF00854           |
| GT*43004P-*48*-**  | 35.1-48Vdc                    | 3.42A                        | 120W                       | XF00830           |

## 7.0 Illustrations

### Illustration 2 - Insulation diagram



| TABLE: Insulation diagram (measured values) <sup>1</sup>                  |   |   |                              |                  |                                     |                                      |                                     |                                      | P <sup>2</sup>   |
|---|---|---|------------------------------|------------------|-------------------------------------|--------------------------------------|-------------------------------------|--------------------------------------|--|
| Pollution degree..... <sup>3</sup>  | 2 <sup>3</sup>  |   |                              |                  |                                     |                                      |                                     |                                      | — <sup>3</sup>   |
| Overtoltage category..... <sup>3</sup>                                    | II <sup>3</sup>   |   |                              |                  |                                     |                                      |                                     |                                      | — <sup>3</sup>   |
| Altitude..... <sup>3</sup>  | 3000m <sup>3</sup>  |   |                              |                  |                                     |                                      |                                     |                                      | — <sup>3</sup>   |
| Additional details on parts considered as applied parts..... <sup>3</sup> | <input checked="" type="checkbox"/> None <input type="checkbox"/> Areas (See Clause 4.6 for details) <sup>4</sup> |   |                              |                  |                                     |                                      |                                     |                                      | — <sup>3</sup>   |
| Area <sup>1</sup>   | Number and type of Means of Protection: MOOP, MOPP <sup>2</sup>   | CTI <sup>1</sup> (IIIb, unless is known) <sup>2</sup> | Working voltage <sup>2</sup> |                  | Required creepage (mm) <sup>2</sup> | Required clearance (mm) <sup>2</sup> | Measured creepage (mm) <sup>2</sup> | Measured clearance (mm) <sup>2</sup> | Remarks <sup>3</sup>   |
|   |   |   | Vrms <sup>2</sup>            | Vpk <sup>2</sup> |                                     |                                      |                                     |                                      |  |
| A <sup>3</sup>  | 1MOPP <sup>3</sup>  | IIIb <sup>3</sup>                                     | 240 <sup>3</sup>             | -- <sup>3</sup>  | 4 <sup>3</sup>                      | 2.5 <sup>7</sup>                     | 4.4 <sup>6</sup>                    | 2.7 <sup>3</sup>                     | Opposite polarity of mains part <sup>3</sup>                                     |
| A <sup>1</sup>  | 1MOPP <sup>3</sup>  | IIIb <sup>3</sup>                                     | 240 <sup>3</sup>             | -- <sup>3</sup>  | 4 <sup>3</sup>                      | 2.5 <sup>7</sup>                     | 4.3 <sup>3</sup>                    | 4.3 <sup>3</sup>                     | Opposite polarity of mains part <sup>3</sup>                                     |
| B <sup>3</sup>  | 2MOPP <sup>3</sup>  | IIIb <sup>3</sup>                                     | 240 <sup>3</sup>             | -- <sup>3</sup>  | 7.9 <sup>4</sup>                    | 5.0 <sup>3</sup>                     | 8.2 <sup>6</sup>                    | 6.6 <sup>3</sup>                     | Accessible metal screws to mains part <sup>3</sup>                               |
| C   | MOPP  | IIIb  | 240                          | 340              | 4.0                                 | 2.5                                  | 5.0                                 | 5.0                                  | Mains parts to PE terminal (On power inlet)                                      |
| C <sup>1</sup>  | MOPP  | IIIb  | 240                          | 340              | 4.0                                 | 2.5                                  | 4.6                                 | 4.6                                  | Mains parts to PE terminal (On PCB trace)  |
| D   | 2MOPP   | IIIb  | 240                          | 340              | 7.9 <sup>4</sup>                    | 5.0                                  | -- <sup>8</sup>                     | -- <sup>8</sup>                      | Internal mains part to accessible outer enclosure (Only for power adapter model) |
| E   | 2MOPP   | IIIb  | 240 <sup>3</sup>             | --               | 7.9 <sup>4</sup>                    | 5.0                                  | 8.0 <sup>5</sup>                    | 8.0 <sup>5</sup>                     | Mains parts to secondary pin-out (Optocoupler)                                   |
| F   | 2MOPP   | IIIb  | 352 <sup>3</sup>             | --               | 10.7 <sup>4</sup>                   | 7.0                                  | 11.5                                | 7.9                                  | Mains parts to secondary pin-out (Transformer)                                   |
| F <sup>2</sup>  | 2MOPP   | IIIb  | 240 <sup>3</sup>             | --               | 7.9 <sup>4</sup>                    | 5.0                                  | 9.0                                 | 9.0                                  | Shield copper foil to secondary pin-out (Transformer)                            |
| G   | MOPP (Each) x 2   | IIIb  | 240 <sup>3</sup>             | --               | 4.0 <sup>4</sup>                    | 2.5                                  | 6.5                                 | 6.5                                  | Mains parts to secondary pin-out (Y capacitor x 2)                               |
| H   | MOPP  | IIIb  | 240 <sup>3</sup>             | --               | 4.0 <sup>4</sup>                    | 2.5                                  | 4.6 <sup>6</sup>                    | 2.5                                  | Secondary parts to 1 <sup>st</sup> Y capacitor pin-out (On PCB trace)            |

## 7.0 Illustrations

### Illustration 2a - Insulation diagram(Cont.)

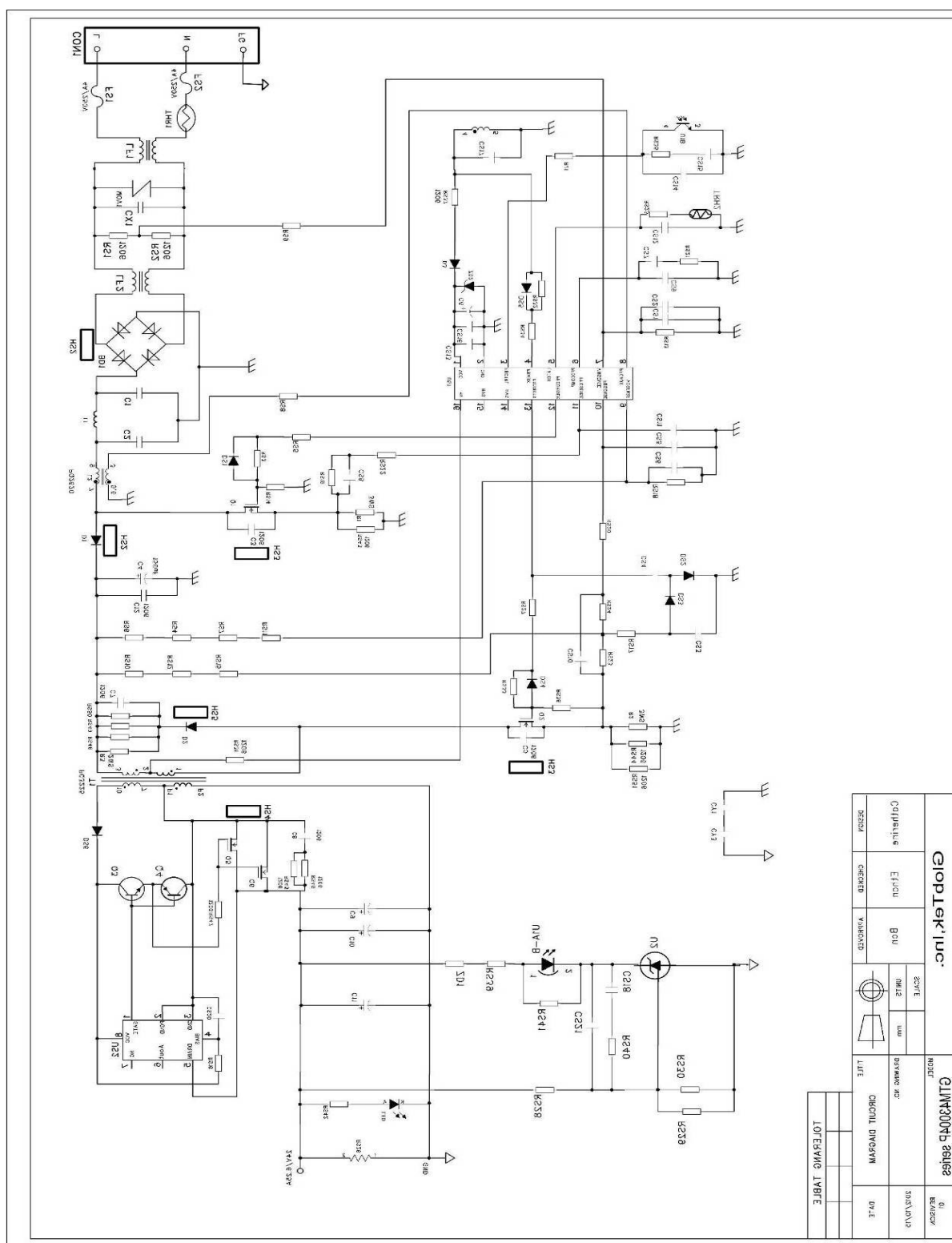
|   |       |      |                  |    |                  |     |                 |                 |   |
|---|-------|------|------------------|----|------------------|-----|-----------------|-----------------|---|
| I | 2MOPP | IIIb | 240 <sup>3</sup> | -- | 7.9 <sup>4</sup> | 5.0 | 8.1             | 8.1             | Mains parts to secondary parts (On PCB trace) |
| J | 2MOPP | IIIb | 240 <sup>3</sup> | -- | 7.9 <sup>4</sup> | 5.0 | -- <sup>9</sup> | -- <sup>9</sup> | Secondary heatsink to mains parts             |
| K | 2MOPP | IIIb | 240 <sup>3</sup> | -- | 7.9 <sup>4</sup> | 5.0 | 8.3             | 8.3             | Primary heatsink to secondary parts           |
| L | 2MOPP | IIIb | Max. 48Vdc       | -- | --               | --  | --              | --              | Accessible parts per 8.4.2 c)                 |

**Note:**

- 1) The same area is evaluated in open frame model. And there is no more difference if not specified.
- 2) Optionally an electromagnetic shield which is copper foil is added around the outside of the coil. It's connected to mains part.
- 3) The working voltage is highest measured value which acquired by testing all the models listed in the report at the rated input voltage, but not less than the rated input voltage.
- 4) Linear interpolation is applied to the determination of required creepage.
- 5) The minimum creepage and clearance is selected from all the types of optocouplers.
- 6) There is a slot min. 1 mm wide between these two parts.
- 7) Multiplication factor for MOOP: 1.14; Multiplication factor for MOPP: 1.00.
- 8) Minimum 0.4 mm thick Mylar sheet wraps around internal conductive parts.
- 9) Two layers of insulating tape or one layer of min. 0.4 mm thickness insulating tube wrap around the secondary heatsink.



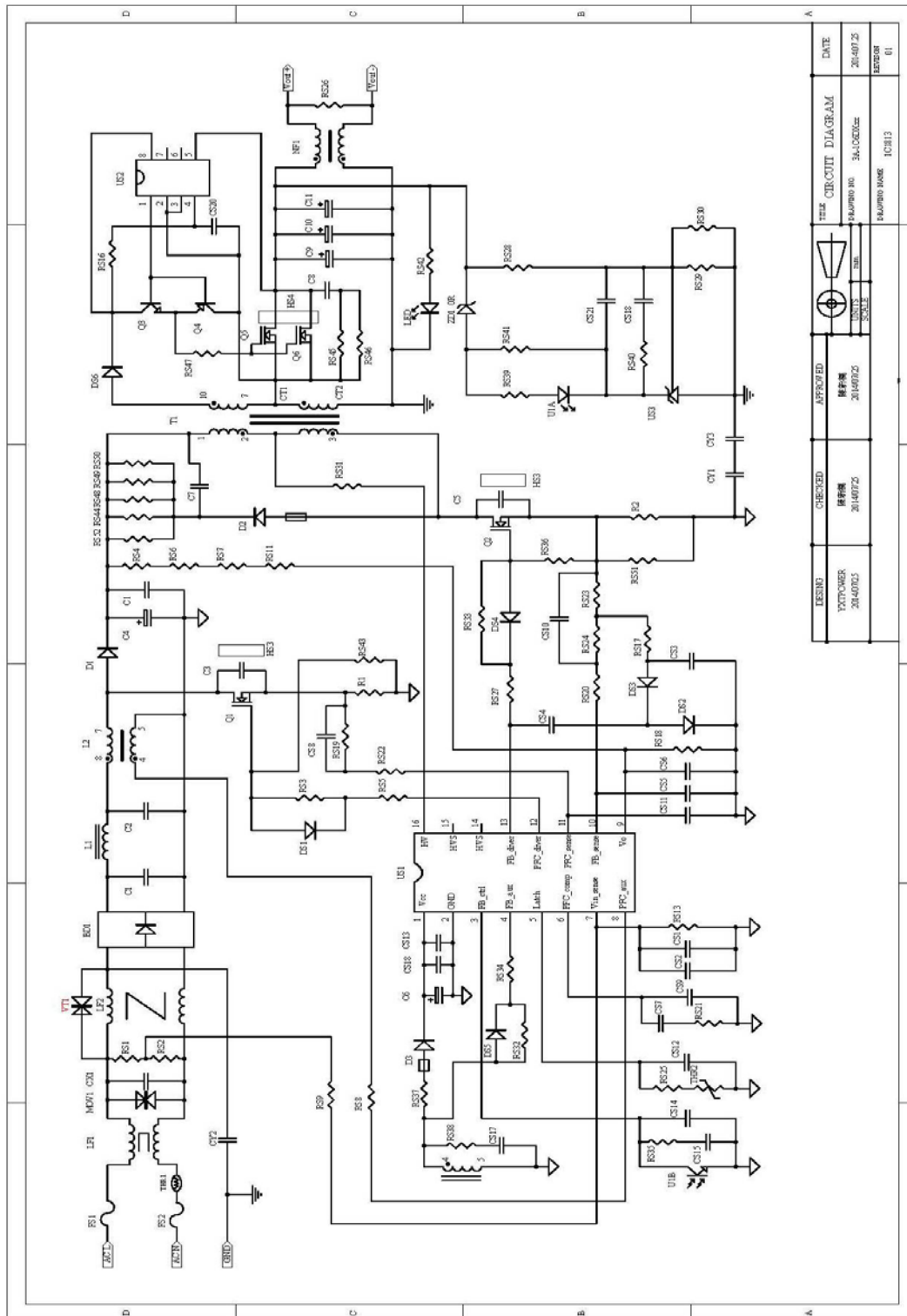
### Illustration 3 - Schematics



## 7.0 Illustrations

### Illustration 3a - Schematics(Cont.)

(Only for GTM43004P-12024-T2)-alternative

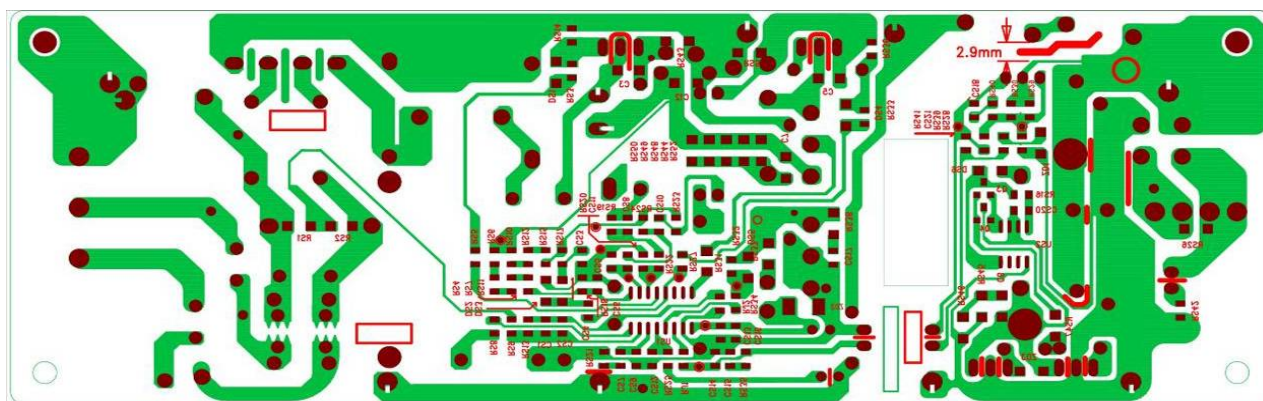
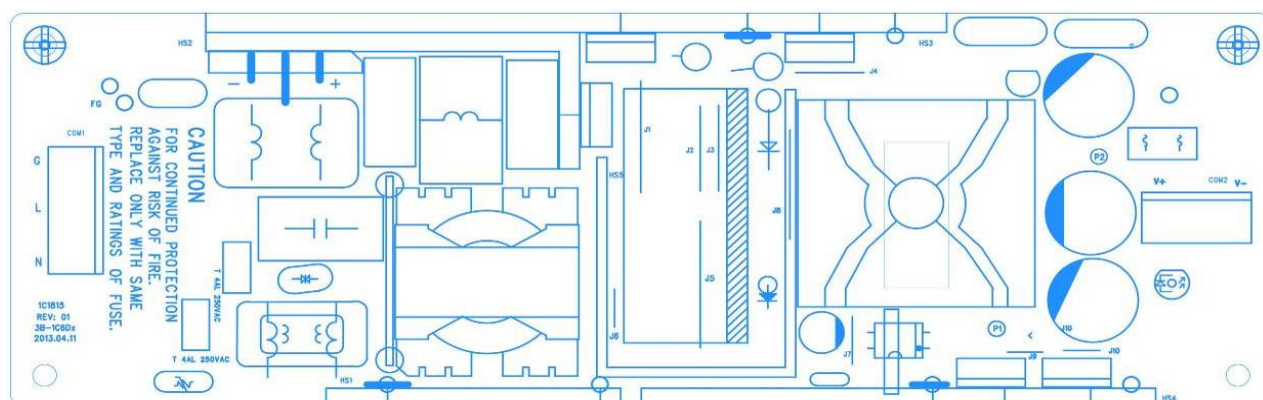


| DESIGN   | CHECKED  | APPROVED | DATE     |
|----------|----------|----------|----------|
| YUICHER  | 陳奇騰      | 陳奇騰      | 20140725 |
| 20140725 | 20140725 | 20140725 | 20140725 |
| SCALE    | 1:1      | 1:1      | 1:1      |
| REVISION | 1        | 1        | 1        |

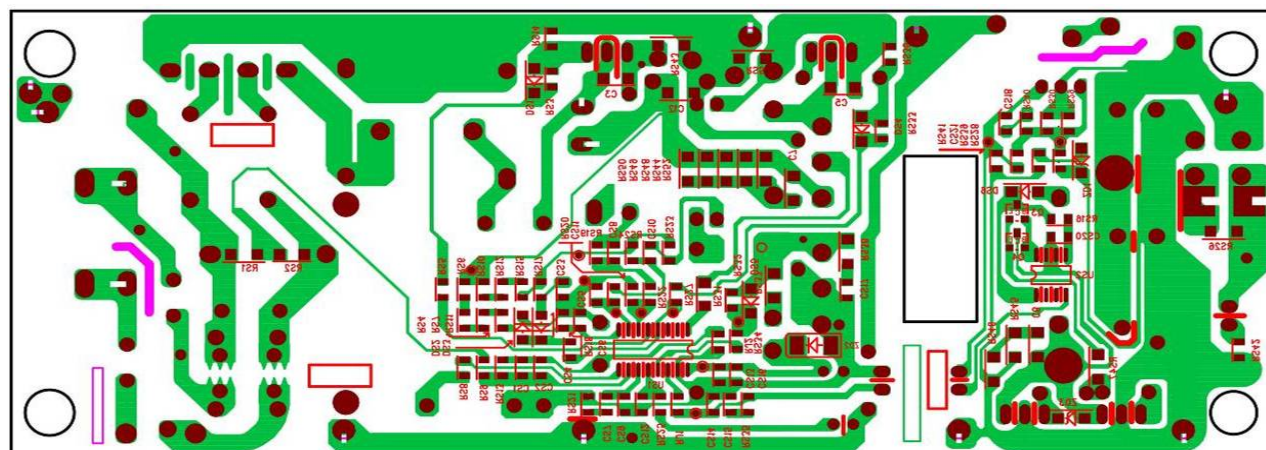
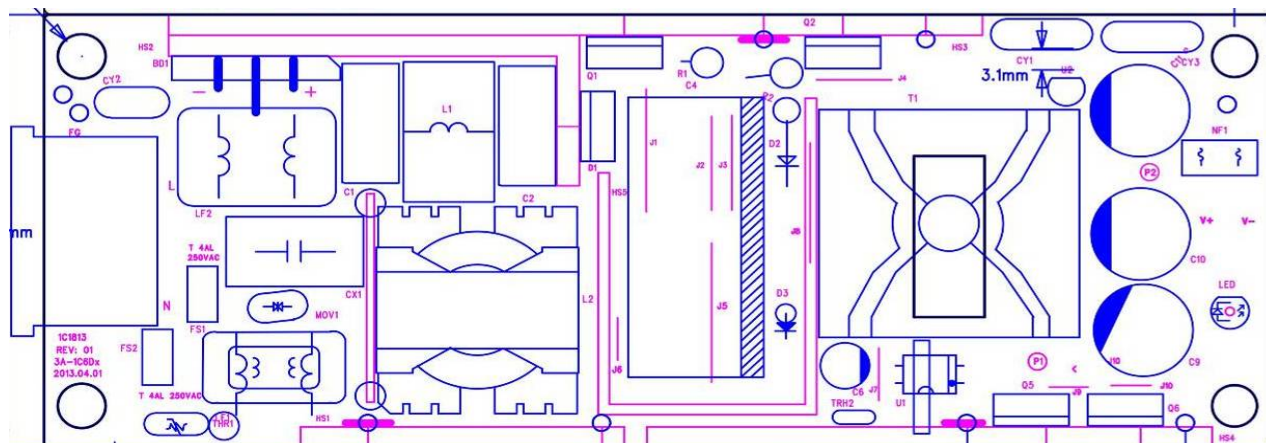
## 7.0 Illustrations

### Illustration 4 - PCB LAYOUT

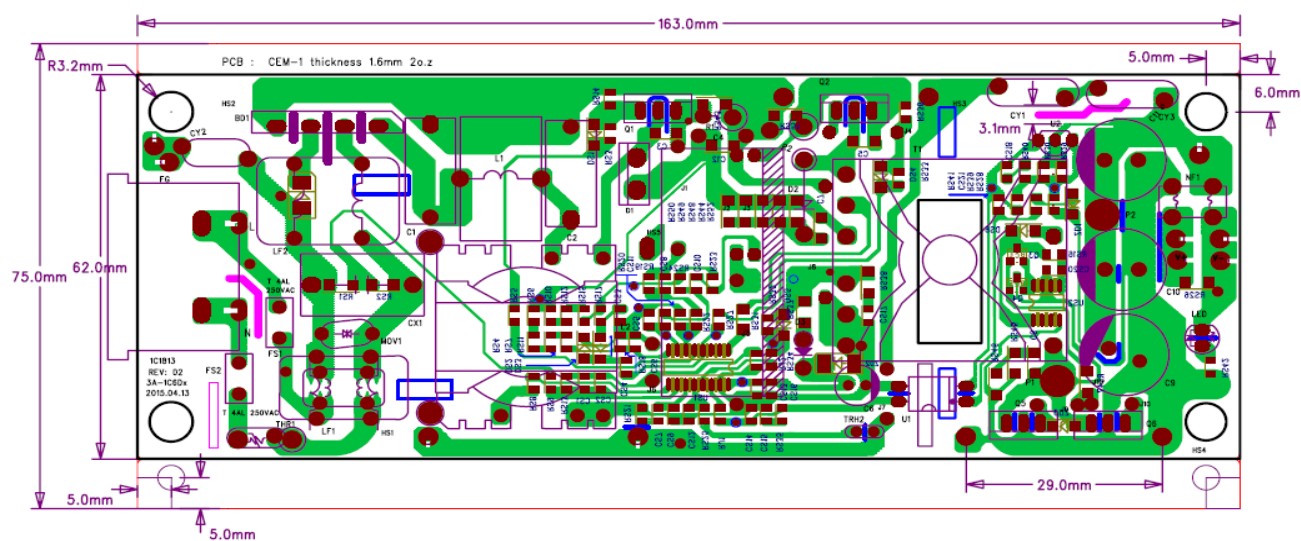
For open frame model



For adapter model



**For adapter model (only for GTM43004P-12024-T2)-alternative**






## 7.0 Illustrations


### Illustration 5 - Marking label



The other models (refer to 2.0) have the same labels except the model number and rating.





For power adapter model, the left one represents Class I model series & the right one represents Class II model series.


**GlobTek®**, Inc.  
MEDICAL POWER SUPPLY


**P/N (料号):**  
**MODEL (型号):** GTM43004P12048-T3  
**INPUT (输入):** 100-240V~, 50 - 60 Hz, 2.0 A  
**OUTPUT (输出):** 48V  $\equiv$  2.5 A  
**CAUTION: INDOOR USE ONLY!**  
(小心: 室内使用)  
ATTENTION: utiliser uniquement en intérieur!


EFFICIENCY LEVEL 

  
RECOGNIZED  
COMPONENT  
  
C LISTED US  
Intertek  
4007497  
CONFORMS TO ANSI/AAMI std. ES60601-1 &  
CERTIFIED TO CAN/CSA std. C22.2 No.60601-1

  
Intertek




EFFICIENCY LEVEL 






RoHS





WWYY    MADE IN CHINA    中国制造


**GlobTek®**, Inc.  
MEDICAL POWER SUPPLY


**P/N (料号):**  
**MODEL (型号):** GTM43004P12048-T2  
**INPUT (输入):** 100-240V~, 50 - 60 Hz, 2.0 A  
**OUTPUT (输出):** 48V  $\equiv$  2.5 A  
**CAUTION: INDOOR USE ONLY!**  
(小心: 室内使用)  
ATTENTION: utiliser uniquement en intérieur!


EFFICIENCY LEVEL 

  
RECOGNIZED  
COMPONENT  
  
C LISTED US  
Intertek  
4007497  
CONFORMS TO ANSI/AAMI std. ES60601-1 &  
CERTIFIED TO CAN/CSA std. C22.2 No.60601-1

  
Intertek



EFFICIENCY LEVEL 



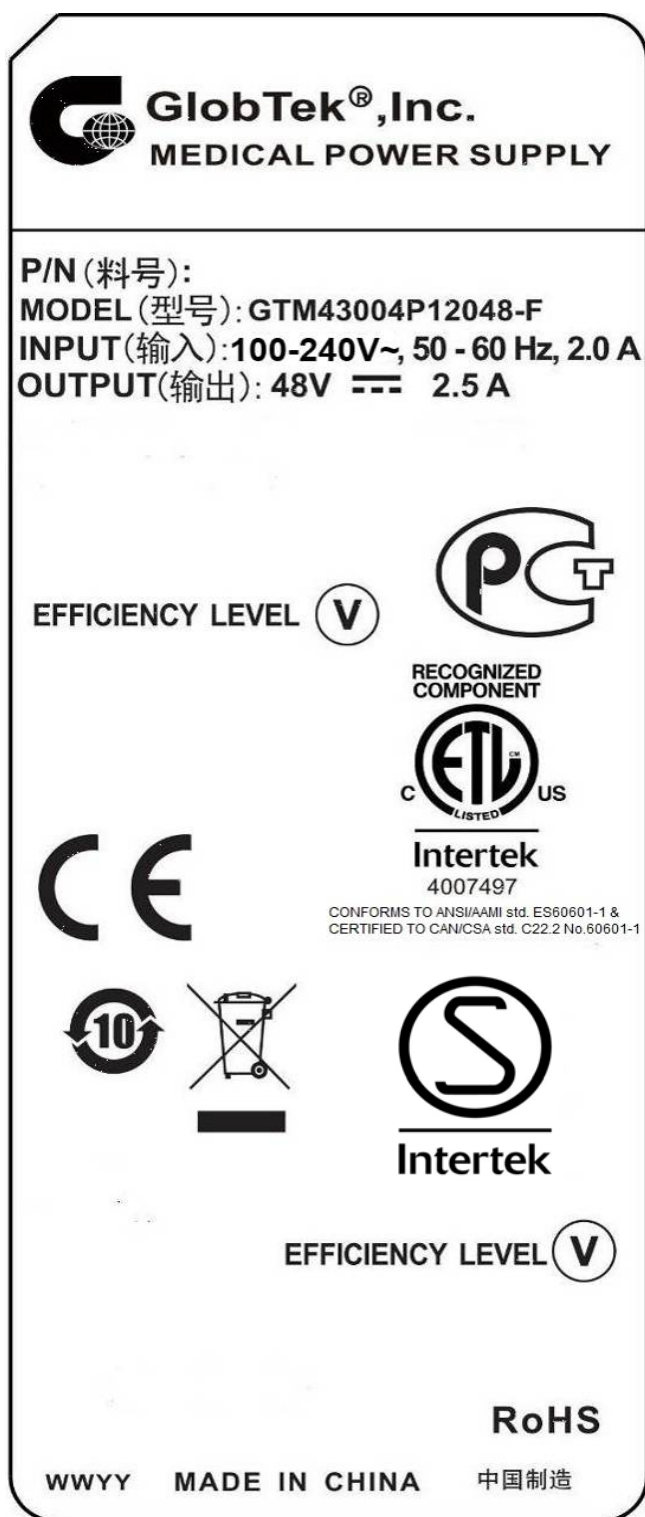
RoHS

WWYY    MADE IN CHINA    中国制造

## 7.0 Illustrations

### Illustration 5a - Marking label (Cont.)

For open frame model



| 8.0 Test Summary  |   |   |             |              |            |
|---|---|---|-------------|--------------|------------|
| Evaluation Period   | 8/5/2015-8/14/2015  |   | Project No. | 150702593SHA |            |
| Sample Rec. Date  | 28-Jul-2015   | Condition   | Prototype   | Sample ID.   | 0150728-01 |
| 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  |   | Version Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance; with AMD 1; 2012/11/08 & 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   |             |              |            |
| Earthing  |   | 8.6.4   |             |              |            |
| Leakage Current Test terminations   |   | 8.7.4   |             |              |            |
| Dielectric Strength Means   |   | 8.8.3   |             |              |            |
| Ball Pressure Test  |   | 8.8.4.1   |             |              |            |
| Creepage & Clearance Measurements   |   | 8.9.4   |             |              |            |
| Surfaces, corners and edges   |   | 9.3   |             |              |            |
| Excessive Temperature   |   | 11.1  |             |              |            |
| Single Fault Conditions   |   | 13.2  |             |              |            |
| Push Test   |   | 15.3.2  |             |              |            |
| Impact Test   |   | 15.3.3  |             |              |            |
| Drop Test   |   | 15.3.4  |             |              |            |
| Moulding Stress Relief  |   | 15.3.6  |             |              |            |
| Transformer Short-Circuit   |   | 15.5.1.2  |             |              |            |
| Transformer Overload  |   | 15.5.1.3  |             |              |            |
| 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:  | Skot Shi         | Reviewed by: | Justin Yu        |
| Title:   | Project engineer | Title:       | Reviewer         |
| Signature:   | <i>Skot Shi</i>  | Signature:   | <i>Justin Yu</i> |

## 9.0 Correlation Page For Multiple Listings

The following products, which are identical to those identified in this report except for model number and Listee name, are authorized to bear the ETL label under provisions of the Intertek Multiple Listing Program.

|              |  |
|--------------|--|
| BASIC LISTEE | GlobTek, Inc.                            |
| Address      | 186 Veterans Dr. Northvale, NJ 07647 USA |
| Country      | USA                                      |
| Product      | Medical Power Supply                     |

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

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

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



## 10.0 General Information

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

### COMPONENTS

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

### LISTING MARK

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

The mark must include the following four items:

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

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

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

Can be used together when both standards are used.

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

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

### MANUFACTURING AND PRODUCTION TESTS

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

### FOLLOW-UP SERVICE

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

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

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

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

### 10.1 Evaluation of Unlisted Components

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

**Note to Intertek Follow Up Inspector: The Component Evaluation Center, CEC, will notify you in writing when these components must be selected and sent to the CEC for re-evaluation**

Ship the samples to:  
Intertek Testing Services Shanghai Limited  
ETL Component Evaluation Center  
Building No. 86, 1198 Qinzhou Road (North)  
Shanghai 200233, China  
Attn: Ms. Dansy Xu

Sample Disposition: Due to the destructive nature of the testing, all samples will be discarded at the conclusion of testing unless, the manufacturer specifically requests the return of the samples. The request for return must accompany the initial component shipment.

## 11.0 Manufacturing and Production Tests

The manufacturer agrees to conduct the following Manufacturing and Production Tests as specified:

### Required Tests

Dielectric Voltage Withstand Test  
Grounding Continuity Test

## 11.1 Dielectric Voltage Withstand Test

### Method

One hundred percent of production of the products covered by this Report shall be subjected to a routine  
The test shall be conducted on products, which are fully assembled. Prior to applying the test potential, all  
The test voltage specified below shall be applied between primary circuits and accessible dead-metal parts. The

### Test Equipment

The test equipment shall incorporate a transformer with an essentially sinusoidal output, a means to indicate the  
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 500VA or more, the applied test potential may be indicated by either:

### **Products Requiring Dielectric Voltage Withstand Test:**

| <u>Product</u>  | <u>Test Voltage</u> | <u>Test Time</u> |
|---|---------------------|------------------|
| Between mains part and secondary circuits for Class II model and open frame model | 4000Vac             | 1 s              |
| Between mains part and secondary circuits (earthing) for Class I model only       | 1500Vac             | 1 s              |

## 11.2 Grounding Continuity Test

### Method

Each product listed below shall be subjected to a test to determine that there is continuity between accessible  
contacts of secondary terminal of the product and the grounding pin of the appliance inlet.

If accessible contacts of secondary terminal (-) are connected, only a single test need be performed. A visual or  
audible device (ohmmeter, buzzer, etc.) may be used to indicate grounding continuity.

### **Products Requiring Grounding Continuity Test:**

Class I model covered by this Report.

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

ED 16.3.15 (1-Jan-13) Mandatory