UL TEST REPORT AND PROCEDURE

| Standard: | UL 60950-1, 2nd Edition, 2014-10-14 (Information Technology Equipment - Safety - Part 1: General Requirements) CAN/CSA C22.2 No. 60950-1-07, 2nd Edition, 2014-10 (Information Technology Equipment - Safety - Part 1: General Requirements) |
|-----------------------------|--|
| Certification Type: | Component Recognition |
| CCN: | QQGQ2, QQGQ8 (Power Supplies for Information Technology Equipment Including Electrical Business Equipment) |
| Complementary CCN: | QQHM2, QQHM8 (Power Supplies, Medical and Dental) |
| | QQJQ2, QQJQ8 (Power Supplies for Use in Audio/Video, Information and Communication Technology Equipment) |
| Product: | Switching Power Supply |
| Model: | GXE600-24 and GXE600-48 May be followed by suffix "abcdefg" (a is /, b is A, c is HD, d is NS, e is FG, f is SF, g is NHV for GXE600-48, and "a", "b", "c", "d", "e", "f", "g" may be blank) (for the details, see General Product Information) |
| Rating: | Input: 100-240Vac, 50-60Hz, 7.0A Output: 24Vdc, 25A (For Model GXE600-24) 48Vdc, 12.5A (For Model GXE600-48) |
| Applicant Name and Address: | TDK-LAMBDA CORP NAGAOKA TECHNICAL CENTER R&D DIV 2704-1 SETTAYA-MACHI NAGAOKA-SHI NIIGATA 940-1195 JAPAN |

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 under the indicated 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.

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Reviewed by: Masatomo Takiyama

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 product covered in this Test Report is a building-in type switching power supply with DC output circuits.

The power supply is intended to be connected to protective earth in the end product via Chassis.

[For QQHM2/8]

The product is component type power supply for built-in type, model GXE600 series, and intended for use in end-product equipment used in a hospital or related health care facility.

This equipment provides One Means Of Patient Protection (1MOPP) between Primary/Secondary and GND, and Two Means Of Patient Protection (2MOPP) between Primary and Secondary.

Model Differences

All the models are identical except for model designation, output rating, T1 secondary plate, and secondary components. No difference in primary circuit.

GXE600-24 and GXE600-48:

May be followed by suffix "abcdefg" (a is /, b is A, c is HD, d is NS, e is FG, f is SF, g is NHV for GXE600-48, and "a", "b", "c", "d", "e", "f", "g" may be blank)

Suffixes are defined as below.

"/" - Separator.

"A" - with metal cover.

"HD" - with coating (not relied upon to reduce spacing)

"NS" - without communication function

"FG" - low leakage with limited capacitance for C2, C3, C5 to C7, C15, C16

"SF" - single fuse (jumper on Neutral line)

"NHV" - applied to GXE600-48 only. Output voltage range 9.6 to 55.2 Vdc

Technical Considerations

- Equipment mobility : for building-in
- Connection to the mains : N/A
- Operating condition : continuous
- Access location : N/A (for building-in)
- Over voltage category (OVC) : OVC II

- Mains supply tolerance (%) or absolute mains supply values : +10%, -10%
- Tested for IT power systems : No
- IT testing, phase-phase voltage (V) : N/A
- Class of equipment : Class I (earthed)
- Considered current rating of protective device as part of the building installation (A) : 20 A
- Pollution degree (PD) : PD 2
- IP protection class : IP X0
- Altitude of operation (m) : up to 5000 m (for QQGQ2/8 and QQJQ2/8), up to 4000 m (for QQHM2/8)
- Altitude of test laboratory (m) : less than 2000 meters
- Mass of equipment (kg) : approximately 1.3
- The product was submitted and evaluated for use at the maximum ambient temperature (Tma) permitted by the manufacturer's specification of: Up to 70 °C which depends on load factor, input voltage and cooling condition. See Enclosed Id. 7-01 for details.
- The product is intended for use on the following power systems: TN
- The mode of operation is continuous
- The product is not suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide.
- The product was not investigated to the following standards or clauses: Biocompatibility, PESS, EMC, Annex Z of EN standards for compliance with the MDD, Electromagnetic Compatibility (IEC 60601-1-2), Risk Management (ISO 14971). [QQHM2/8]

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:

- The following Production-Line tests are conducted for this product: Electric Strength
- The end-product Electric Strength Test is to be based upon a maximum working voltage of: Primary-Earthed Dead Metal: 380 Vrms / 584 Vpk, Primary-Secondary: 379 Vrms / 648 Vpk.
- The following secondary output circuits are SELV: All models' output.
- The following secondary output circuits are at hazardous energy levels: 24V output, 48V output
- The following secondary output circuits are at non-hazardous energy levels: AUX_5V
- The power supply terminals and/or connectors are: Suitable for factory wiring only
- The maximum investigated branch circuit rating is: 20 A
- The investigated Pollution Degree is: 2
- Proper bonding to the end-product main protective earthing termination is: Required
- An investigation of the protective bonding terminals has: Not been conducted
- The following input terminals/connectors must be connected to the end-product supply neutral: TB1 terminal "AC (N)"
- The following end-product enclosures are required: Electrical / Fire / Mechanical
- Necessity of retesting temperature related tests shall be considered in the end-product application.
- The following magnetic devices (e.g. transformers or inductor) are provided with an IEC 60085 (equivalent to UL1446) insulation system with the indicated rating greater than Class 105(A): T2, T3, T4, T5 (Class 130(B)), L5 (Class 155(F))
- Line to Line Capacitors (C1 and C4) may have variations in capacitance up to 1.5 uF and 0.68 uF

respectively. Therefore, consideration shall be given in controlling the capacitance value in the endproduct application with respect to capacitance discharge issue.

- Primary to Ground Capacitors (C2, C3, C15, C16, C5, C6, and C7) may have variations in capacitance up to 470pF, and 680pF respectively. Therefore, consideration shall be given in controlling the capacitance values in end product application with respect to touch Current issue.
- Humidity conditioning has been conducted by tropical condition.
- Cautionary marking for double pole/neutral fusing shall be provided in end product application. [Except for model with suffix "SF"]
- The following output circuits are at ES1 energy levels : Output of Models with GXE600-24 and GXE600-48/NHV
- The following output circuits are at ES2 energy levels : Output of Models with GXE600-48
- The following output circuits are at PS3 energy levels : Output of Models GXE600-24, GXE600-48 and GXE600-48/NHV
- The following output circuits are at PS1 energy levels : AUX Output 5V
- Classification of PIS has not been conducted. Therefore, all electrical components and conductors including printed wirings were assumed to be arcing/resistive PIS.
- This component has been evaluated in "control of fire spread" method assuming appropriate fire
 enclosure is provided in end product. Unless the fire enclosure is made of non-combustible or V-0
 material, the separation from the PIS shall be considered.
- Overcurrent protection in accordance with cl. 8.11.5 shall be prepared in the end product, if applicable. [QQHM2/8]
- The equipment is not provided with disconnecting means in accordance with cl. 8.11.1. It shall be considered in the end product. [QQHM2/8]
- The output circuits have not been evaluated for direct patient connection (Type B, BF or CF). Additional requirements may be required if used for connection to applied parts. [QQHM2/8]
- Consideration should be given to measuring the temperature on power electronic components and transformer windings when the equipment is used with the end product. The end product shall ensure that the equipment is used within its ratings. [QQHM2/8]
- Instructions for use shall be checked in the end product. [QQHM2/8]
- Temperature test was conducted without test corner. The acceptability of risk in conjunction to temperature testing with test corner shall be considered in the end product. [QQHM2/8]
- Final installation of this equipment should comply with the enclosure, mounting, marking, spacing and separation requirements. In addition, Temperature, Leakage Current, Dielectric Voltage Withstand and Interruption of this equipment tests should be considered as part of the end product evaluation. [QQHM2/8]
- Risk Management Process in accordance with cl. 4.2 shall be evaluated in the end product. [QQHM2/8]
- The equipment has been judged on the basis of the required creepage and clearance according to cl. 8.9 in IEC 60601-1 Edition 3.1 (2012) that covers the end application for which the component was designed. [QQHM2/8]
- The equipment has been evaluated as a Class I, continuous operation, IPX0, and not been evaluated for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. Additional evaluations shall be considered if the equipment is intended for classifications other than these. [QQHM2/8]
- In convection condition, there is no requirements for clearances between the equipment and surroundings. As requested by the manufacturer, adequate clearances were kept. [QQHM2/8]

- In forced air condition, the customized box with fan motor was prepared by the manufacturer (fan motor: manufacturer SANYO DENKI CO., LTD., type 9A0612SD041). The distance between the equipment and fan motor was 500 mm.
- In forced air condition, fan motor (fan motor: manufacturer SANYO DENKI CO., LTD., type 9A0612SD041) was set at 9.0 Vdc, 0.12 A (equivalent to 1.0 m/s). Other conditions may require additional tests.
- Main output circuit is non-hazardous voltage level in accordance with cl. 8.4.2 c). (GXE600-24abcdefg and GXE600-48abcdefNHV) [QQHM2/8]
- Main output circuit is at hazardous energy level (240 VA) in accordance with cl. 8.4.2 c). [QQHM2/8]
- AUX output circuit is non-hazardous and energy level (240 VA) in accordance with cl. 8.4.2 c). [QQHM2/8]
- AUX output circuit complies with power availability (15 W) in accordance with cl. 13.1.2. [QQHM2/8]

Additional Information

Maximum Normal Load: Output rated load

There are various conditions of output loads, and four patterns of installation conditions. For the details, see Enclosure Miscellaneous id.7-01.

There is auxiliary output with 5 Vdc, 1 A (no deviation). In addition to main output, the auxiliary output was continuously loaded in operating condition.

Model GXE600-24 was tested with output voltage range of 4.8 - 28.8 Vdc (max. 25A, maximum 600 W), Model GXE600-48 was tested with output voltage range of 9.6 - 57.6 Vdc (max. 12.5A, maximum 600 W), Model GXE600-48/NHV was tested with output voltage range of 9.6 - 55.2Vdc (max. 12.5A, maximum 600 W).

The Clearances and Creepage Distances have additionally been assessed for suitability up to 5000 m elevation (for QQGQ2/8 and QQJQ2/8), and up to 4000 m elevation (for QQHM2/8).

Additional Standards

The product fulfills the requirements of: The product fulfills the requirements of: UL 62368-1, 2nd Edition, 2014-12-01, CAN/CSA C22.2 No. 62368-1-14, 2nd Edition, 2014-12. ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14

| Markings and instructions | |
|--|--|
| Clause Title | Marking or Instruction Details |
| Power rating - Ratings | Ratings (voltage, frequency/dc, current) |
| Power rating - Model | Model Number |
| Power rating - Company identification | Listee's or Recognized company's name, Trade Name, Trademark or File Number |