Description

UL TEST REPORT AND PROCEDURE

Standard:	ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14
Certification Type:	Component Recognition
CCN:	QQHM2 / QQHM8
Complementary CCNs:	
Product:	Switching Power Supply
Model:	CUT35-zxxxxxxx; CUT35J-zxxxxxxx (z = 522 or 5FF; xxxxxxx = /, A, B, L, T, other alphanumeric character, symbol or blank)
Rating:	Refer to Enclosure ID Miscellaneous-(01) for details.
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 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 as applicable.

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

Prepared by: MyongHwan Noh, Project Handler Reviewed by: Jun Orito, Reviewer

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 component type switching mode power supply series intended for use in class I construction of medical equipment.

Output Rating:

[For CUT35-522 and CUT35J-522]
CH1: 5 to 5.25V, maximum 3.0A, maximum 15.0W
CH2: 12V, maximum 1.2A, maximum 14.4W
CH3: -12V, maximum 0.85A, maximum 10.2W
(Total output power is maximum 35.4W, and then CH2, CH3 outputs' total power is maximum 20.4W.)

[For CUT35-5FF and CUT35J-5FF]
CH1: 5 to 5.25V, maximum 3.0A, maximum 15.0W
CH2: 15V, maximum 1.0A, maximum 15.0W
CH3: -15V, maximum 0.65A, maximum 9.75W
(Total output power is maximum 34.5W, and then CH2, CH3 outputs' total power is maximum 19.5W.)

CH1: Changeable by the adjustable variable resistor (VR51).
CH2, CH3: Fixed.
Refer to the Report Modifications page for any modifications made to this report.

Model Differences

Model CUT35-zxxxxxxx is basic model.

Model CUT35J-zxxxxxxx is identical to Model CUT35-zxxxxxxx except for model name.

Suffix "z" of all models denotes output voltage. (z = 522 or 5FF)

Suffix "xxxxxxx" of all models denotes as follows. (xxxxxxx = /, A, B, L, T, other alphanumeric character, symbol or blank)
/: Separator of model name letters, not related specification of equipment
A: Provided with chassis and cover
B: Provided with base plate
L: Provided with chassis under PWB
T: Provided with terminal block
Other alphanumeric character, symbol: For market purposes, no construction differences and no safety impact.
Brank: Provided with JST connector or TE connectivity connector

Additional Information

This Test Report was based on the CB Test Certificates (Ref. Certif. Nos. DE 2-021261 dated 2016-12-08

and DE 2-021261-M1 dated 2017-03-21) and Test Reports (Ref. Nos. 50059578 001 dated 2016-12-08 and 50059578 002 dated 2017-03-20), which were prepared by TÜV Rheinland LGA Products GmbH and submitted by the CB Scheme.
The test results and clause verdicts of the above noted report were reviewed and found to comply with the applicable Standard IEC 60601-1:2005 (Third Edition) + Am 1:2012. As a result the clause verdicts and test results for this report were noted as N/A and have been referred to the TÜV Rheinland LGA Products GmbH. Test Reports for details. All test data have been retained in UL's files.

Technical Considerations

- The product was investigated to the following additional standards: N/A
- The following additional investigations were conducted: N/A
- The product was not investigated to the following standards or clauses: Clause 17: Electromagnetic Compatibility (IEC 60601-1-2), Clause 14, Programmable Electronic Systems, Biocompatibility (ISO 10993-1), Risk Management (ISO 14971), Usability (IEC 60601-1-6)
- The following accessories were investigated for use with the product: N/A
- The degree of protection against harmful ingress of water is ordinary, IPX0.
  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.
  Although product specification says 85-265 Vac for input voltage range, test was conducted at 90-264 Vac (+/- 10 %).
  The maximum specified operational ambient temperature is 70 °C. For derating curve, see Enclosure ID Miscellaneous-(02)

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:

- - Overcurrent protection in accordance with clause 8.11.5 shall be prepared in the end product. Also, opposite polarities between live and neutral (1MOOP) shall be evaluated in the end product.

  - The equipment has been evaluated for use at altitudes up to 3,000m and pollution degree 2.

  - The product was submitted and tested for use at the manufacturer's recommended ambient temperature (Tmra). See Enclosure ID Miscellaneous-(02) for additional details regarding out derating depending on ambient temperature or input voltage.

  - This power supply has been judged on the basis of the required creepage and clearances in the Standard for Medical Electrical Equipment, AAMI ES / CSA 60601-1, sub-clause 8.9.

  - 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.

  - Instructions for use shall be checked in the end product.

  - This unit is a power supply intended for building in. Final installation should comply with the enclosure, mounting, marking, spacing and separation requirements. In addition, Temperature, Leakage Current, Dielectric Voltage Withstand and Interruption of the Power Supply tests should be considered as part of the end product evaluation.

  - The output circuit has not evaluated for connecting to Applied Parts. For end products intended to connect the output circuit to Applied Parts, suitable evaluation of the separation, leakage current, dielectric voltage withstand and related requirements should be conducted.

  - Proper bonding to protective earthing terminal of end product shall be provided.

  - Input and output connectors are not intended for field-wiring connection. They are only intended for factory-wiring inside the end product.

- Dielectric Strength Test in the end product is to be based upon the maximum working voltage of: T1: 277 Vrms, 528 Vpk; T2: 293 Vrms, 564 Vpk.

- 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.

- The following end-product enclosures are required: Electrical, Fire

- All secondary output circuits are non-hazardous voltage, and non-hazardous energy level (240 VA) in accordance with sub-clause 8.4.2 c).

- The maximum investigated branch circuit rating is 20 A. If used on a branch circuit greater than this, additional testing may be necessary.

- 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.

- Risk Management Process in accordance with clause 4.2 shall be evaluated in the end product.

- 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.

- The following magnetic devices (e.g. transformers or inductor) are provided with an UL1446 insulation system with the indicated rating greater than Class A (105°C): T1, T2 (Class F), L1 (130°C)

- The maximum continuous power supply output (Watts) relied on forced air cooling from: See Enclosure ID Miscellaneous-(02) for details.

- X-Capacitors (C1, C2) may have variation in capacitance up to 0.22 µF (C1), 0.1 µF (C2). Therefore, consideration shall be given in controlling the capacitance value in the end-product application with respect to capacitance discharge issue.

- Y-Capacitors (C3, C4, C5) may have variations in capacitance up to 1000 pF (C3, C4), 2200 pF (C5) respectively. Therefore, consideration shall be given in controlling the capacitance values in end product application with respect to touch Current issue.