Description

UL TEST REPORT AND PROCEDURE

Standard:	ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CAN/CSA C22.2 No. 60601-1:14
Certification Type:	Component Recognition
CCN:	QQHM2 / QQHM8
Complementary CCNs:	
Product:	Switching Power Supply
Model:	CME30A-zzxxxxxxx; CUS30M-zzxxxxxxx (zz = 12, 15, 18, 24, 36 or 48; xxxxxxx = /, A, U, ADJ, M, CO, SF, P, other alphanumeric character, symbol or blank)
Rating:	Refer to Enclosure ID Miscellaneous-(001) 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: Atsushi Fuchita, Project Handler Reviewed by: Thorsten Creter, 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 or II construction of medical equipment.
- For earthed construction (Class I), the equipment need to be reliably earthed and professionally installed and fixed with metal screws.
- For non-earthed construction (Class II), no earthing connection is required. The equipment need to be fixed so, that it is insulated from any unearthed accessible conductive part by reinforced insulation.

Output Rating:
12 V (10.8 - 13.2 V), maximum 2.5 A (Maximum 30.0 W) (for CUS30M-12, CME30A-12)
15 V (13.5 - 16.5 V), maximum 2.0 A (Maximum 30.0 W) (for CUS30M-15, CME30A-15)
18 V (16.2 - 19.8 V), maximum 1.7 A (Maximum 30.6 W) (for CUS30M-18, CME30A-18)
24 V (21.6 - 26.4 V), maximum 1.25 A (Maximum 30.0 W) (for CUS30M-24, CME30A-24)
36 V (32.4 - 39.6 V), maximum 0.84 A (Maximum 30.24 W) (for CUS30M-36, CME30A-36)
48 V (43.2 - 52.8 V), maximum 0.63 A (Maximum 30.24 W) (for CUS30M-48, CME30A-48)

Refer to the Report Modifications page for any modifications made to this report.

Model Differences

Model CUS30M-zzxxxxxxx is basic model.

Model CME30A-zzxxxxxxx is identical to Model CUS30M-zzxxxxxxx except for model name.

Suffix "zz" of all models denotes output voltage. (zz = 12, 15, 18, 24, 36 or 48)

Suffix "xxxxxxx" of all models denotes as follows. (xxxxxxx = /, A, U, ADJ, M, CO, SF, P, other alphanumeric character, symbol or blank)
/: Separator of model name letters, not related specification of EUT
A: Provided with chassis and cover
U: Provided with U shape chassis
ADJ: Provided with output adjust
M: Provided with Molex connector
CO: Provided with PWB coating
SF: Provided without Fuse (F1B)
P: Provided with solderable copper pins in place of connectors
Other alphanumeric character, symbol or blank: For market purposes, no construction differences and no safety impact.

Additional Information

This Test Report was based on the CB Test Certificate (Ref. Certif. No. DE 2-022164 dated 2017-08-11 and DE 2-022164-M1 dated 2018-12-14) and Test Report (Ref. No. 50088663 001 dated 2017-08-09 and 50088663 002 dated 2018-12-14), 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.

Since the client requested us to change the description of Insulation Sheet in list of critical components and addition of four openings on the insulation sheet that were not included in the above CB Test Reports, only Humidity Conditioning (5.7), Dielectric Voltage Withstand test (8.8.3) and measurements of insulation distances (8.9) were considered necessary.

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-(002).

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 5,000m and pollution degree 2.

  - The product was submitted and tested for use at the manufacturer's recommended ambient temperature (Tmra). See Enclosure ID Miscellaneous-(002) 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. (only for earthed construction)

- 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: 250 Vrms, 504 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 or II, 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 (Class B), L1, L2 (130°C)

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

-Y-Capacitors (C2, C3, C4, C5) may have variations in capacitance up to 1000 (for C2, C3) / 1500 (for C4, C5) pF. Therefore, consideration shall be given in controlling the capacitance values in end product application with respect to Touch Current issue.

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
Power Input	Amps, VA, or Watts
Output	Rated output voltage, power, frequency.

Special Instructions to UL Representative

Note to Field Representative at ALPS LOGISTICS FACILITIES CO LTD (Sub. #100553-903):
ALPS LOGISTICS FACILITIES CO LTD may receive complete UL Recognized Component products from other Manufacturer within the same procedure volume.
ALPS LOGISTICS FACILITIES CO LTD is allowed to modify the items marked '#' in Table 8.10, and new nameplate label containing UL Recognized Marking is relabeled. In this case, the modified product is marked the Factory ID "F" on product or smallest unit container in which the product is packed.
Then, the following Special Inspection procedure is to be applied.
Special Inspection procedure: Inspect in accordance with the following steps.
- Inspect the fact that ALPS LOGISTICS FACILITIES CO LTD received complete UL Recognized Component products.
- Inspect only the items which were modified at ALPS LOGISTICS FACILITIES CO LTD.

Production-Line Testing Requirements

Required	Test	Model/Part Exempt from Test	Additional Details
Yes	Grounding Continuity	None	-
Yes	Dielectric Voltage Withstand	None	-
No	Patient Circuit Dielectric Voltage Withstand	All models	-

Solid-State Components		
The following solid-state components that can be disconnect from the remainder of the circuitry during either Dielectric Voltage Withstand Test:	Parts to be disconnected for test:	Specific Test:
	N/A	N/A
	-	-
	-	-
	-	-
	-	-

Sample and Test Specifics for Follow-Up Tests at UL

The following tests shall be conducted in accordance with the Generic Inspection Instructions

Plastic Enclosure or Part	Test	Sample(s)	Test Specifics
None	NA	NA	NA