

Description

UL TEST REPORT AND PROCEDURE

Standard:	ANSI/AAMI ES60601-1 (2005/(R)2012 + A1:2012, C1:2009/(R)2012 + A2:2010/(R)2012) - Amendment 1 - Revision Date 2012/08/21; CAN/CSA-C22.2 No. 60601-1:14 - Edition 3 - Revision Date 2014/03
Certification Type:	Component Recognition
CCN:	QQHM
Complementary CCNs:	
Product:	Medical Grade Power Supply
Model:	CME350P-1000-abcdef, CUS350MP-1000-abcdef; where a is 24, 30, 36 or 48 and "bcdef" is set of optional suffix (b is /; c is T; d is A or L; e is CO2; f is SF, and "b", "c", "d", "e" and "f" maybe blank) (See General Product Information for more details)
Rating:	Input: 100 - 240Vac, 50-60Hz; 6.2A Output: <CME350P-1000-24 / CUS350MP-1000-24> Nominal: 24Vdc (23.5-26.9Vdc), 14.6A (Peak: 24Vdc, 41.7A) <CME350P-1000-30 / CUS350MP-1000-30> Nominal: 30Vdc (26.5-30.5Vdc), 11.65A (Peak: 30Vdc, 33.3A) <CME350P-1000-36 / CUS350MP-1000-36> Nominal: 36Vdc (35.5-42.5Vdc), 9.7A (Peak: 36Vdc, 27.7A) <CME350P-1000-48 / CUS350MP-1000-48 > Nominal: 48Vdc (44.5-48.5Vdc), 7.3A (Peak: 48Vdc, 20.9A)
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.

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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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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 under tests is component type power supply for built-in type, models CME350P-1000-abcdef / CUS350MP-1000-abcdef are intended for use in end-product equipment used in a hospital or related health care facility. Product comes with 1 main output (24Vdc/30Vdc/36Vdc/48Vdc) with positive and negative terminals; and 1 aux output (5Vdc).

During evaluation, the product operating condition was continuously operated with the respective main output load; and 5Vdc aux output (0.3A).

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

Model Differences

CME350P-1000-abcde is identical to CUS350MP-1000-abcef; other than model designation. Other than the options "bcdef"; CME350P-1000-24, CME350P-1000-30, CME350P-1000-36, CME350P-1000-48 have similar construction; except for model designation, T1 internal construction (related to number of secondary winding turns) and output ratings.

Options "abcdef" are defined as below:

-a is output voltage; can be 24, 30, 36 or 48

- b is separator; can be / or blank

- c is type of input connector; can be T (Terminal block type) or blank

- d is type of chassis; can be A (Chassis covering both component and solder sides), L (L-shaped chassis covering solder side only) or blank (with base plate only)

- e is type of functional coating; can be CO2 (Double sided coating on both sides of PWB, not for safety purpose) or blank

- f is type of fuse configuration; can be SF (Single Fuse, F1) or blank (Double fused; F1 and F2)

Additional Information

Project 4789869018 (Apr 2021)

Refer to CBTR ref E309264-D1050-1/A1/C0-CB issued on 2021-03-25; CBTC ref #DK-107035-M1-UL issued on 2021-03-25; for the evaluation.

1) Addition of the models with 30Vdc and 36Vdc output

CME350P-1000-30 / CUS350MP-1000-30

CME350P-1000-36 / CUS350MP-1000-36

Document review is conducted to confirm the transformer (T1) used in the new models are of same construction, with primary circuitry must be exact same as previous evaluated models; and the only difference in the transformers are only at the number of secondary winding turns.

2) Add alternate insulation tape source (TERAOKA SEISAKUSHO CO LTD, 650S#25)

Dielectric testing is done for reference for the new insulation tape source; the insulation tape is not used for insulation purpose in the construction. Result is referenced from the evaluation in E309264-D1050-1/A1/C0-

CB

3) Add optional insulation sheet sources between L1 line filter and C8, C9 bulk caps
No testing or review is required as this insulation sheet is not relied upon for safety

4) Max operating ambient rating are increased for the following configurations:

Models without /A suffix at 100% load:

- Mounting B (45 -> 50)
- Mounting C (45 ->50)
- Mounting E (35 -> 40)

Models with /A suffix at 100% load:

- Mounting A and C (40 -> 45)
- Mounting B (40 -> 50)
- Mounting D and E (35 -> 45)

No testing is required as the document review shows that even with the shifting up of the operating ambient temperature, the results are still within limits. The test table results in the report has been updated for the affected Temperature tests. Report model information has been updated accordingly for the affected mounting positions.

The LOCC (List Of Critical Components) is updated to

- control the new transformer (T1) for Item 15; for (1)
- control the new alternate source of insulation tape for (2)
- indicate the optional insulation sheet for (3)

5) Removing 2 factories (Alps Logistics Facilities Co Ltd and Sendan Electronics Mfg Co Ltd) as per manufacturer request

6) Item #34 Coating material is added to LOCC as per manufacturer request

No evaluation is required as component is controlled for UL Recognized mark, with standards; and component not required for additional evaluation in the product standard.

Project 4789727534 (Dec'2020)

CB report conversion to NRTL (UL, cUL Mark).

This report is to be read in conjunction with E309264-D1050-1/A0/C0-CB issued on 2020-12-10; CBTC ref #DK-107035-UL issued on 2020-12-11.

Construction review work was referenced to previous project 4789236109; as the construction is exactly the same and the review work has already been done considering US and CAN National differences.

All tests have been conducted in previous project 4789236109; see below for Additional Details

Full evaluation of CME350P-1000-24, CME350P-1000-48, CUS350MP-1000-24, CUS350MP-1000-48 in UL International-Singapore Pte Ltd

For CME350P-1000-24/CUS350MP-1000-24:

Maximum Rated Load: Unit operates continuously with output loaded 24V Vdc, 14.6 A.

Maximum Normal Load A: Unit operates continuously with output loaded 100%; 23.5 Vdc, 14.6 A.

Maximum Normal Load B: Unit operates continuously with output loaded 100%; 26.9 Vdc, 13.1 A.

Maximum Normal Load C: Unit operates continuously with output loaded 45%; 23.5 Vdc, 6.6 A.

Maximum Normal Load D: Unit operates continuously with output loaded 45%; 26.9 Vdc, 5.9 A.

Maximum Normal Load E: Unit operates continuously with output loaded 35%; 23.5 Vdc, 5.2 A.

Maximum Normal Load F: Unit operates continuously with output loaded 35%; 26.9 Vdc, 4.6 A.

Maximum Normal Load G: Unit operates continuously with output loaded 30%; 23.5 Vdc, 4.4 A.

Maximum Normal Load H: Unit operates continuously with output loaded 30%; 26.9 Vdc, 4.0 A.

For CME350P-1000-48/CUS350MP-1000-48:

Maximum Rated Load: Unit operates continuously with output loaded 48V Vdc, 7.3 A.

Maximum Normal Load A: Unit operates continuously with output loaded 100%; 44.5 Vdc, 7.3 A.

Maximum Normal Load B: Unit operates continuously with output loaded 100%; 48.5 Vdc, 7.3 A.

Maximum Normal Load C: Unit operates continuously with output loaded 45%; 44.5 Vdc, 3.3 A.

Maximum Normal Load D: Unit operates continuously with output loaded 45%; 48.5 Vdc, 3.3 A.
 Maximum Normal Load E: Unit operates continuously with output loaded 35%; 44.5 Vdc, 2.6 A.
 Maximum Normal Load F: Unit operates continuously with output loaded 35%; 48.5 Vdc, 2.6 A.
 Maximum Normal Load G: Unit operates continuously with output loaded 30%; 44.5 Vdc, 2.2 A.
 Maximum Normal Load H: Unit operates continuously with output loaded 30%; 48.5 Vdc, 2.2 A.

Maximum Operating Temperature, Tma (°C)

Models without /A suffix:

35 °C for 100 % load (Rated Load, Condition A and B), Mounting Position D and E;
 40 °C for 100 % load (Rated Load, Condition A and B), Mounting Position F;
 45 °C for 100 % load (Rated Load, Condition A and B), Mounting Position B, C
 50 °C for 100 % load (Rated Load, Condition A and B), Mounting Position A;
 70 °C for 45 % load (Condition C and D), Mounting Position B;
 70 °C for 35 % load (Condition E and F), Mounting Position A, C and F;
 70 °C for 30 % load (Condition G and H), Mounting Position D and E;

Models with /A suffix:

35 °C for 100 % load (Rated Load, Condition A and B), Mounting Position D, E and F;
 40 °C for 100 % load (Rated Load, Condition A and B), Mounting Position A, B and C;
 70 °C for 30 % load (Condition G and H), Mounting Position A, B, C, D, E and F

Per manufacturer's request, below tests were performed on CME350P-1000-48 to simulate end system scenario:

Forced air cooling Loading (Refer to Enclosures - Miscellaneous (005), for air flow diagram on external fan):

@264Vac, Output 10.4A with external fan
 @90Vac, Output 10.4A with external fan

Peak Loading with conventional cooling:

Cycles of output current as below respective configuration to simulate corresponding Prms;
 @85Vac, Cycles of Output: Turn on: 16.7A, 5s, Adjusted to: 5.7A, 495s (Prms=280W)
 @110Vac, Cycles of Output: Turn on: 16.7A, 5s, Adjusted to: 7.2A, 495s (Prms=350.4W)
 @265Vac, Cycles of Output: Turn on: 16.7A, 5s, Adjusted to: 7.2A, 495s (Prms=350.4W)
 @170Vac, Cycles of Output: Turn on: 20.9A, 3s, Adjusted to: 7.1A, 297s (Prms=350.4W)
 @265Vac, Cycles of Output: Turn on: 20.9A, 3s, Adjusted to: 7.1A, 297s (Prms=350.4W)

Peak Loading with forced air cooling (Refer to Enclosures - Miscellaneous (005), for air flow diagram on external fan):

Cycles of output current as below respective configuration to simulate corresponding Prms;
 @85Vac, Cycles of Output: Turn on: 16.7A, 5s, Adjusted to: 8.3A, 495s (Prms=400W) with external fan
 @110Vac, Cycles of Output: Turn on: 16.7A, 5s, Adjusted to: 10.4A, 495s (Prms=500W) with external fan
 @265Vac, Cycles of Output: Turn on: 16.7A, 5s, Adjusted to: 10.4A, 495s (Prms=500W) with external fan
 @170Vac, Cycles of Output: Turn on: 20.9A, 3s, Adjusted to: 10.3A, 297s (Prms=500W) with external fan
 @265Vac, Cycles of Output: Turn on: 20.9A, 3s, Adjusted to: 10.3A, 297s (Prms=500W) with external fan

Refer to product specifications in Enclosure - Miscellaneous for relevant Peak output configuration

Technical Considerations

- The product was investigated to the following additional standards:
- The following additional investigations were conducted: Manufacturer's verification request to investigate the product with CME350P-1000-48 in Mounting A position to simulate end system scenario from Prms=280W to Prms=500W.
 See Additional Information in General Product Information (GPI) of report for configurations.
- The product was not investigated to the following standards or clauses: Risk Management,

Biocompatibility (ISO 14971), PESS (IEC 62304), EMC (IEC 60601-1-2), Annex ZZ of EN standards for compliance with the MDD

- The following accessories were investigated for use with the product: N/A
- - Due to same construction between this product models (CME350P-1000-24, CME350P-1000-48, CUS350MP-1000-24, CUS350MP-1000-48) for MED certification and product models (ZWP350-1000-24, ZWP350-1000-48) for ITE certification; documentation such as drawing and component specifications in this project are using ITE project documents directly.
 - For some of critical components, EN standards were used to verify the compliance. The EN standards were harmonized to IEC standard, and technically equivalent.
 - When submitting this Test Report to other Certification Body, the manufacturer is responsible for providing any additional information that the Body may need in order to issue its Mark, including testing for compliance with the applicable collateral standards.
 - Refer to Product specification in Enclosure-Miscellaneous for the output derating details which include the maximum specified operational ambient temperature.
 - 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.
 - Input voltage deviation is +/-10 % of rated voltage (100-240Vac); 85 Vac (-15 %) was excluded from this evaluation by the manufacturer's request.
 - Output power is max 350.4W
 - For 24 Vout model, output voltage deviation is 23.5 - 26.9Vdc.
 - For 30Vout model, output voltage deviation is 26.5 - 30.5Vdc.
 - For 36Vout model, output voltage deviation is 35.5 - 42.5Vdc.
 - For 48 Vout model, output voltage deviation is 44.5 - 48.5Vdc.
 - Product has been evaluated for 1 MOPP insulation between Outputs and Ground

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 product has been evaluated on the basis of the required Creepage and Clearance according to Clause 8.9 in the ANSI/AAMI ES60601-1 (2005/(R)2012 + A1:2012, C1:2009/(R)2012 + A2:2010/(R)2012), CAN/CSA-C22.2 No. 60601-1:14 that cover the end application for which the component was designed; using Pollution Degree 2. The clearance requirement was evaluated for compliance for 4,000m altitude operation.
 - The product provides the following MOPP (Means Of Patient Protection): The power supply was evaluated for 2 MOPP requirements between primary and secondary (Transformer T1's Core is considered floating), In addition, 1 MOPP (insulation from MAINS) is declared by manufacturer between outputs and ground; and verified in the investigation See insulation diagram for details.
 - Overcurrent protection in accordance with whole of cl. 8.11.5 shall be prepared in the end product.

- For product with single fuse option (i.e. with suffix /SF); Class I end product must be evaluated for presence of fuse/over-current release in both Line and Neutral supply. Also, opposite polarities between live and neutral (1MOOP) shall be evaluated in the end product.
- Considerations to the applied parts requirement shall be evaluated in the end-product. The output circuits (both main and aux output) 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 product was evaluated using 20A as branch circuit protection. Additional evaluation is required if it is used on branch circuit with greater protection.
- Dielectric Strength Test in the end product is to be based upon the maximum working voltage of: Pri-Gnd 250Vrms, 354Vpk; Pri-Sec 266Vrms, 692Vpk
- All main output circuits are non-hazardous voltage, but all at hazardous energy level (240 VA) in accordance with cl. 8.4.2 c
- Evaluation involving forced air cooling for the manufacturer request tests are conducted using fan with 2.2 m/s air flow applied towards capacitors C8/C9. Effect of forced air cooling on the product is to be re-evaluated during end product investigation
- The following end-product enclosures are required: Electrical, Fire, Mechanical.
- 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.
- 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.
- Proper bonding to protective earthing terminal of end product shall be provided.
- Final installation of this equipment (including accessibility of output connectors) should comply with the enclosure, mounting, marking (Durability, Legibility), 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.
- Risk Management Process in accordance with cl. 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 OBJY2 insulation system with the indicated rating greater than Class A (105 °C): T1 (Class F), T2 (Class F)

