Description

UL TEST REPORT AND PROCEDURE

Standard:	AAMI ES60601-1:2005,ES60601-1:2005/AMD1 1:2012 , ES60601-1:2005/AMD2:2021, CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14
Certification Type:	Component Recognition
CCN:	QQHM2 / QQHM8
Complementary CCNs:	
Product:	Switching Power Supply
Model:	CUS800My-zxxxxxxx, CME800Ay-zxxxxxxx, CUS1000Myzxxxxxxx,CME1000Ay-zxxxxxxx (y = blank; z = 12,24,36,48;xxxxxxx = /CO, /CO2, /G, /SF, /CQC other alphanumeric character, symbol or blank) Suffix options example for "xxxxxxx" would be used shown below may be used together; Blank denotes for standard model; /CO denotes for single side PWB coating; /CO2 denotes for double side PWB coating; /SF denotes for single fuse; /G denotes for low earth Leakage current; /CQC denotes for CQC approval; other alphanumeric character,symbol for market purposes, no construction differences and no safety impact.
Rating:	Refer to Enclosure ID Miscellaneous for details.
Applicant Name and Address:	TDK-Lambda (China) Electronics Co Ltd No.95,Zhujiang Rd, Xinwu District Wuxi 214028, China

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: Zack Wu, Project Handler Reviewed by: Skye Mo, 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 PSU is a component type switching mode power supplies intended for use with the earthed construction medical equipment.
For earthed construction (Class I), the PSU need to be reliably earthed and professionally installed and fixed with metal screws.
Refer to the Report Modifications page for any modifications made to this report.

Model Differences

Model CME800Ay-zxxxxxxx is identical to model CUS800My-zxxxxxxx except for model name.
Model CME1000Ay-zxxxxxxx is identical to model CUS1000My-zxxxxxxx except for model name.

All models are identical, except for the optional chassis, cover, turns of Transformer and the rating of some components that results in different output ratings. See Model List below for details. All models are identical, except of the optional chassis, cover, turns of Transformer and the rating of some components which results in different output ratings. See Model List below for details.
CUS800M series and CUS1000M series have same PCB and circuit topology. Compared to CUS1000M series, CUS800M series have no additional heatsink on PFC heatsink for D1 and SCR1 and no additional busbar on bottom side. CUS800M series and CUS1000M series have different heatsinks for output rectifier components.

Additional Information

This Test Report was based on the CB Test Certificate (Ref. Certif. No. DE 2-040461 dated 2023-11-15) and Test Report (Ref. No. CN23WOWH 001 dated 2023-11-06), 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 + A1:2012 + A2:2020. 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)
- 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 maximum specified operational ambient temperature is 70 °C.
  This PSU subject to this evaluation is not a medical device or system on its own right, but a component intended for building into such. Risk assessment was therefore not subject of this investigation. It shall be carried out for final medical electrical equipment or system.
  The insulation system of the PSU was evaluated for compliance with the MEANS OF PATIENT PROTECTION (MOPP).
  Compliance with IEC / EN 60601-1-2 shall be evaluated during the end system evaluation.
  The product is for building-in equipment, the overall compliance shall be investigated in the complete medical electrical equipment or system, in particular:
  - Fire enclosure
  - Mechanical enclosure
  - Electrical enclosure
  Some components are pre-certified, which have been evaluated according to the relevant requirements of IEC 60601-1, are employed in this product.
  The equipment does not have circuits for direct connection to the patient and not is intended for use in the presence of flammable anesthetic mixtures with air, oxygen or nitrous oxide.
  The input circuit includes one fuse (F1A) in the Line conductor and the other fuse (F1B) is optional in neutral conductor. Consideration shall be given in the end-use product regarding addition of the second fuse having the same or better characteristics in order to comply with fusing requirements of Clause 8.11.5 of the standard.
  The others see Enclosed Miscellaneous-Recommend by manufacturer

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:

- -When installed in an end-product, consideration must be given to the following:
  Scope of Power Supply evaluation defers the following clauses to be determined as part of the end product
  investigation:
  Clause 7.2.7 ELECTRICAL INPUT POWER FROM THE SUPPLY MINS,
  Clause 7.5 SAFETY SIGNS,
  Clause 7.6 SYMBOLS,
  Clause 7.9 ACCOMPANYING DOCUMENTS,
  Clause 9 PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS,
  Clause 10 PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS,
  Clause 12 ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS,
  Clause 14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS),
  Clause 16 ME SYSTEMS,
  Risk Management was excluded from this investigation
  Risk Controls/ Engineering Considerations for component power supply:
  For use only in or with complete equipment where the acceptability of the combination is determined by the CB Testing Laboratory, when installed in an end-product, consideration must be given to the

following: For Power Supplies with No RM: End product Risk Management Process to include consideration of requirements specific to the Power Supply.
For Power Supplies with No RM: End product Risk Management Process to consider the acceptability of risk for the following components that were identified as High-Integrity Component: i.e. Fuse (F1A).
For Power Supplies with No RM: End product Risk Management Process to consider the need for simultaneous fault condition testing.
For Power Supplies with No RM: End product Risk Management Process to consider the need for different orientations of installation during testing.
For Power Supplies with No RM with Exposure Condition outside of Humidity Range: Power Supply tested in 40°C, 95%RH. End product Risk Management Process to determine risk acceptability criteria.
For Power Supplies with No RM and Insulating Materials: End product to determine the acceptability of risk in conjunction to insulation to resistance to heat, moisture, and dielectric strength.
For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the movement of components as part of the power supply.
For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the movement of conductors as part of the power supply.
For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the routing of wires away from moving parts and sharp edges as part of the power supply.
For Power Supplies with No RM and Not tested with Test Corner: Temperature Test was conducted without Test Corner. End product to determine the acceptability of risk in conjunction to temperature testing without test corner as part of the power supply.
For Power Supplies with No RM or Units without Cleaning/Disinfection Methods: End product to determine the acceptability of risk in conjunction to the Cleaning and Disinfection Methods as part of the power supply.
For Power Supplies with No RM or Units with Liquids: End product to determine the acceptability of risk in conjunction to the Leakage of Liquids as part of the power supply.
For Power Supplies with No RM or Units with Indicators: End product to determine the acceptability of risk in conjunction to the Arrangement of Indicators as part of the power supply.
For Power Supplies with No RM or Units with Enclosures: End product to determine the acceptability of risk in conjunction to the results of Mechanical Testing conducted as part of the power supply.
For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the selection of components as it pertains to the intended use, essential performance, transport, storage conditions as part of the power supply.
For Power Supplies with Thermal Cut-off and No RM: End product to determine the acceptability of risk in conjunction to the use of Thermal Cut-off and Overcurrent releases as part of the power supply.
For Power Supplies with Pre-set components and No RM: End product to determine the acceptability of risk in conjunction to the use of Pre-set controls as part of the power supply.