UL TEST REPORT AND PROCEDURE

Standard:	AAMI ES60601-1:2005, ES60601-1:2005/AMD1:2012 , 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 (Power Supplies, Medical and Dental - Component)
Complementary CCN:	N/A
Product:	Switching Power Supply
Model:	CUS1200My-zxxxxxx, CME1200Ay-zxxxxxx, CUS1200-zxxxxxx,CWS1200-zxxxxxx. y=blank, denotes for standard model; z = 24, 36, 48; denoting output voltage 24Vdc, 36Vdc or 48Vdc; (where “xxxxxxx” can be any alphanumeric character, symbol or blank, non safety relevant information.) 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 only for market purposes, no construction differences and no safety impact.
Rating:	Refer to Enclosure ID Miscellaneous 07-01 for details.
Applicant Name and Address:	TDK-LAMBDA (CHINA) ELECTRONICS CO LTD NO.95, ZHUJIANG RD, XINWU DISTRICT WUXI JIANGSU 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.

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: Ivan Wan / 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.

Model Differences

Model CME1200Ay-zxxxxxxx & CUS1200-zxxxxxxx & CWS1200-zxxxxxxx are identical to model CUS1200My-zxxxxxxx except for model name.

Models with different outputs are identical, except for the turns of transformer and the different output ratings. The appearance of cooling fins for 48V is different to 24V or 36V.

See enclosure ID Miscellaneous 07-01 for details.

Full tests were performed on model CUS1200M-24, CUS1200M-36 & CUS1200M-48.

Test Item Particulars

Classification of installation and use.....:	Fixed
Supply Connection.....:	N/A (to be considered in end-use product)
Device type (component/sub-assembly/ equipment/ system) .....:	Component
Intended use (Including type of patient, application location) .....:	To supply regulated power, no patient connection
Mode of operation.....:	Continuous
Accessories and detachable parts included .....:	None
Other options include.....:	None

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 product is not suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide.
- The maximum specified operational ambient temperature is 70 °C. For derating curve, see Enclosure ID Miscellaneous-(07-04).
  The product can be operated sea level up to 5000m, the minimum clearance see insulation diagram for details.

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:
- -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 a component type switching power supply, the overall compliance shall be investigated in the complete end system/equipment, in particular as:
  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. Overall consideration needed to re-check 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.

Additional Information

This Test Report was based on the CB Test Certificate (Ref. Certif. No. DE 2-044325 dated 2025-04-15) and Test Report (Ref. No. CN25D84W 001 dated 2025-04-15), 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.

Additional Standards

The product fulfills the requirements of: National standard AAMI ES60601-1:2005,AAMI ES60601-1:2005/AMD1:2012, AAMI ES60601-1:2005/AMD2:2021;
Canadian National standard: 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;
National standard JIS T 0601-1:2023

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
Alternating current	
Supply Frequency	Rated frequency range in hertz
Power Input	Amps, VA, or Watts
Output	Rated output voltage, power, frequency.
Special Instructions to UL Representative N/A	