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:	CUS200M-zxxxxxxx, CME200A-zxxxxxxx, CUS150M1-zxxxxxxx, CME150A-zxxxxxxx (z = 12, 18, 24, 36, or 48, xxxxxxx = /, T, M, MR, R, J, JR, L, A, F, CO, CO2, S1, S2, other alphanumeric character, symbol, or blank) (for details, see General Product Information)
Rating:	<Input> 100-240 VAC~, 3.0 A, 50-60 Hz (CUS200M and CME200A), 100-240 VAC~, 1.8 A, 50-60 Hz (CUS150M1 and CME150A) <Output> (CUS200M, CME200A) - 12 Vdc, 16.7 A, - 18 Vdc, 14 A, - 24 Vdc, 10.5 A, - 36 Vdc, 7.0 A, - 48 Vdc, 5.3 A (CUS150M1, CME150A) - 12 Vdc, 12.5 A, - 18 Vdc, 8.4 A, - 24 Vdc, 6.3 A, - 36 Vdc, 4.2 A, - 48 Vdc, 3.2 A
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: Nikon Li, Project Handler Reviewed by: Cynthia Xiao / Claire Xiao, 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 switching power supply, model CUS200M-zxxxxxxx, CME200A-zxxxxxxx, CUS150M1-zxxxxxxx, CME150A-zxxxxxxx, and intended for use in end-product equipment used in a hospital or related health care facility.

Details of output ratings are as follows.
(CUS200M, CME200A)
- 12 Vdc (11.7 - 12.6 Vdc), maximum 16.7 A, maximum 200.4 W (for convection cooling and forced air cooling),
- 18 Vdc (17.6 - 18.9 Vdc), maximum 11.2 A, maximum 201.6 W (for convection cooling),
- 18 Vdc (17.6 - 18.9 Vdc), maximum 14.0 A, maximum 252.0 W (for forced air cooling),
- 24 Vdc (23.5 - 25.2 Vdc), maximum 8.4 A, maximum 201.6 W (for convection cooling),
- 24 Vdc (23.5 - 25.2 Vdc), maximum 10.5 A, maximum 252.0 W (for forced air cooling),
- 36 Vdc (35.2 - 37.8 Vdc), maximum 5.5 A, maximum 198.0 W (for convection cooling),
- 36 Vdc (35.2 - 37.8 Vdc), maximum 7.0 A, maximum 252.0 W (for forced air cooling),
- 48 Vdc (47.0 - 50.4 Vdc), maximum 4.2 A, maximum 201.8 W (for convection cooling),
- 48 Vdc (47.0 - 50.4 Vdc), maximum 5.3 A, maximum 254.4 W (for forced air cooling),

(CUS150M1, CME150A)
- 12 Vdc (11.7 - 12.6 Vdc), maximum 12.5 A, maximum 150.0 W (for convection cooling),
- 18 Vdc (17.6 - 18.9 Vdc), maximum 8.4 A, maximum 151.2 W (for convection cooling),
- 24 Vdc (23.5 - 25.2 Vdc), maximum 6.3 A, maximum 151.2 W (for convection cooling),
- 36 Vdc (35.2 - 37.8 Vdc), maximum 4.2 A, maximum 151.2 W (for convection cooling),
- 48 Vdc (47.0 - 50.4 Vdc), maximum 3.2 A, maximum 153.6 W (for convection cooling)

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

Model Differences

CME150A is identical to CME200A except for model designation, input/output power, cooling condition *), the specification of some components (both primary and secondary circuits) to give effect to output power. For details, see Enclosure ID Miscellaneous-(03).
*) CME200A: Convection or forced air cooling, CME150A: Convection cooling.

CME150A is identical to CUS150M1 except for model designation and minor change in secondary circuit.

CME200A is identical to CUS200M except for model designation and minor change in secondary circuit.

For each model, output 12, 18, 24, 36, and 48 Vdc differ in secondary assembly of transformer (T1), resistance of R161, 162, 168, 170 in primary circuit, and secondary circuit.

Suffix “zxxxxxxx” is defined as below. (z = 12, 18, 24, 36, or 48, xxxxxxx = /, T, M, MR, R, J, JR, L, A, F, CO, CO2, S1, S2, other alphanumeric character, symbol, or blank)

- z: Output voltage 12, 18, 24, 36, or 48,
- /: Separator of model name letters, not related specification of EUT,
- T: CN1 with type TL100 series,
- M: CN1 with type 5273 series, 5277 series, 5096 series,
- MR: CN1 with type 5273 series, 5277 series, 5096 series in reverse direction,
- R: CN1 with type VH series or AMP economy power connector series in reverse direction,
- J: CN1 with type VH series,
- JR: CN1 with type VH series in reverse direction,
- L: Chassis,
- A: Chassis and cover,
- F: ON/OFF control and DC OK signal for CUS150M1, CME150A only,
- CO: Printed wiring board coating on solder side,
- CO2: Printed wiring board coating on both side,
- S1: Two-pin input connector and FG tab,
- S2: Improvement for input voltage dip,
- Other alphanumeric character, symbol: Marketing purpose only, no design changes,
- Blank: CN1 with type VH series or AMP economy power connector series

Additional Information
For derating curve, see Enclosure ID Miscellaneous-(01) and (02).

Report Amendment 1, Project 4790797975:

The A1 test report was modification based on E508584-D1001-1/A0/C0-UL as Technical Amendment to:
1. Add trademark and test record in Enclosure, refer to Miscellaneous - (004) for detail;
2. Add Alternate source of Y-Capacitors (C2, 3, 5, 9, 53): MURATA MFG CO LTD / RA series;
3. Add Alternate source of Optocoupler (PC101, 102, 103, 104): Everlight Electronics Co., Ltd. / EL101 and Lite-On Technology Corporation / LTV-10XX;
4. Add Alternate source of bobbin material for T1, T2: SUMITOMO BAKELITE CO LTD / PM-9630
5. Manufacturer name changed Connector (CN1), Fuses (F1A, F1B), Varistor (SA1) and X-Capacitor (C1, 4);
6. Correct the technical data for X-Capacitor (C1, 4);
7. Add alternate source of X-Capacitor (C1, 4): PANASONIC CORPORATION, PANASONIC CORPORATION OF NORTH AMERICA / ECQUL series and TDK (Zhuhai FTZ) Co., Ltd. / B3293# series or B3293 series.
All the changes will not affect the previously insulation data. Through by engineering assessment that no additional tests were deemed necessary to the follows. RM risk management is not applicable for the product. No tests were considered necessary.

Original report:
This is UL/cUL application under ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 and CAN/CSA-C22.2 NO. 60601-1:14, using TUV Rheinland CB test report, Report Reference No. 15081719 001 (2015-11-23) with Ref. Certif. No. DE 2-019607, and its amendment 1, Report Reference No. 15081719 002 (2016-09-29) with Ref. Certif. No. DE 2-019607-M1 under IEC 60601-1, 3,1 edition with the following modifications.
- Correction of manufacturer for fuse (F1A, F1B) from EVER ISLAND ELECTRIC CO LTD & WALTER ELECTRIC to WALTER ELECTRONIC CO LTD,
- Deletion of type B3293 for X-Capacitor (C1, 4),
- Deletion of type ECQUL series for X-Capacitor (C1, 4),
- Deletion of type LE-FL series for X-Capacitor (C1, 4),
- Deletion of type PA series for X-Capacitor (C1, 4),
- Deletion of choke (L1), TDK-LAMBDA CORP,
- Deletion of choke (L1), CLICK TECHNOLOGY CO LTD,
- Deletion of choke (L1), SHANGHAI MEIXING ELECTRONICS CO., LTD,
- Deletion of choke (L2), TDK-LAMBDA CORP,
- Deletion of choke (L2), CLICK TECHNOLOGY CO LTD,
- Deletion of choke (L2), SHANGHAI MEIXING ELECTRONICS CO., LTD,
- Deletion of line filter (L3), TDK-LAMBDA CORP,

- Deletion of line filter (L3), SHANGHAI MEIXING ELECTRONICS CO., LTD,
- Deletion of line filter (L3) (for CUS150M1 and CME150A only), TDK-LAMBDA CORP,
- Deletion of line filter (L3) (for CUS150M1 and CME150A only), SHANGHAI MEIXING ELECTRONICS CO., LTD,
- Deletion of choke (L4), TDK-LAMBDA CORP,
- Deletion of choke (L4), SHANGHAI MEIXING ELECTRONICS CO., LTD,
- Deletion of choke (L5), TDK-LAMBDA CORP,
- Deletion of choke (L5), SHANGHAI MEIXING ELECTRONICS CO., LTD,
- Deletion of type BCK2801-2601/x (for 36 V) for transformer (T1), SHANGHAI MEIXING ELECTRONICS CO., LTD,
- Deletion of type BCK2801-2601/x (for 36 V) for transformer (T1), ZHANGJIAGANG HUA YANG ELECTRONICS CO., LTD.,
- Deletion of optional treatment for transformer (T2)
- Addition of suffix "/", "F", "CO", "S2"
- Change of output voltage tolerance range in each model. As it is more restricted, TUV-Rh test report can cover the compliance.

Based on the previously conducted tests and the review of product technical documentation including photos, schematics, wiring diagrams and the similar, it has been determined that the equipment continues to comply with the standard, and the modifications above would not give impact to product safety.

In TUV-Rh test report, it included construction A and B. However, only construction B is subject to this UL/cUL evaluation by the applicant`s request.

There is no change in silk and pattern trace layouts in all models.

Chassis and cover are optional to all models.

Transformers (T1, 2) are common in all models.

Output voltage ranges under tests:
(CUS200M, CME200A)
- 12 Vdc (11.4 - 12.6 Vdc), maximum 21.0 A, maximum 252.0 W,
- 18 Vdc (17.6 - 19.8 Vdc), maximum 14.0 A, maximum 252.0 W,
- 24 Vdc (22.8 - 26.4 Vdc), maximum 10.5 A, maximum 252.0 W,
- 36 Vdc (34.2 - 39.6 Vdc), maximum 7.0 A, maximum 252.0 W,
- 48 Vdc (45.6 - 52.8 Vdc), maximum 5.3 A, maximum 254.4 W,

(CUS150M1, CME150A)
- 12 Vdc (11.4 - 12.6 Vdc), maximum 12.5 A, maximum 150.0 W,
- 18 Vdc (17.1 - 19.8 Vdc), maximum 8.4 A, maximum 151.2 W,
- 24 Vdc (22.8 - 26.4 Vdc), maximum 6.3 A, maximum 151.2 W,
- 36 Vdc (34.2 - 39.6 Vdc), maximum 4.2 A, maximum 151.2 W,
- 48 Vdc (45.6 - 52.8 Vdc), maximum 3.2 A, maximum 153.6 W

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: 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 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-(01) and (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:

- =AdditionalInfoResultsmay be required if used for connection to applied parts.
  - The following end-product enclosures are required: Electrical, Fire, Mechanical.
  - The maximum investigated branch circuit rating is 20 A. If used on a branch circuit greater than this, additional testing may be necessary.
  - 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.
  - The equipment has been evaluated for use under Pollution degree 2, and at altitude up to 4000 m.
  - 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.
  - Input and output connectors are not intended for field-wiring connection. They are only intended for factory-wiring inside the end product.
  - Final installation of this equipment should comply with the enclosure, mounting, marking, 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 judged on the basis of the required creepage and clearance according to cl. 8.9 in IEC 60601-1 Edition 3.1 (2012) that covers the end application for which the component was designed.
  - 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 B)
  - Maximum working voltage that were applied for dielectric strength test and cl./cr. distances are maximum 363 Vrms, 544 Vpeak for CUS200M and CME200A, and 338 Vrms, 524 Vpeak for CUS150M1, CME150A between primary and secondary/earthed dead metal.
  - Non-hazardous voltage level in accordance with cl. 8.4.2 c): All models
  - Non-hazardous energy level in accordance with cl. 8.4.2 c): CUS150M1, CME150A
  - Hazardous energy level in accordance with cl. 8.4.2 c): CUS200M and CME200A

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 with '#' 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.
- Inspect new nameplate label.

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