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: 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.
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.

For project 4791516537 E508584-D1008-1/A1/C0-UL
Amendment 1:
1. Correct the typo error from ‘B825’ to ‘T825’ for Primary Terminal Block (TB1) in the List of critical components. See Table 8.10 for details.
2. Add a new model ‘T302 series’ for Primary Terminal Block (TB1), which is identical to the previous model except the appearance.See Table 8.10 for details.

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.

  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:

- -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.

Test Report issued under the responsibility of:

IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	
Report Number ....:	E508584-D1008-1/A1/C0-UL
Date of issue ....:	2024-01-09;2024-10-28(A1/C0)
Total number of pages...................:	170
Name of Testing Laboratory preparing the Report......................:	UL-CCIC Company Limited No. 2, Chengwan Road, Suzhou Industrial Park, 215122, Suzhou China
Applicant's name...........................:	TDK-Lambda (China) Electronics Co Ltd
Address ....:	No.95,Zhujiang Rd, Xinwu District Wuxi 214028 China
Test specification:	
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
Test procedure ....:	UL Certification
Non-standard test method………..:	N/A
TRF template used ....:	IECEE OD-2020-F1:2020, Ed.1.3
Test Report Form No......................:	IEC60601_1U
Test Report Form(s) Originator ....:	UL(US)
Master TRF.....................................:	2023-08-24

General disclaimer:

The test results presented in this report relate only to the object tested.
This report shall not be reproduced, except in full, without the written approval of the Issuing NCB. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.

Test item description........................:	Switching Power Supply	
Trade Mark(s) ....:	Trademark image(s): TDK·Lambda	
Manufacturer ....:	Same as Applicant	
Model/Type reference.......................:	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.	
Ratings...:	Refer to Enclosure ID Miscellaneous for details.	
Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):		
[X] **UL Testing Laboratory:**		
Testing location/ address .... :	UL-CCIC Company Limited No. 2, Chengwan Road, Suzhou Industrial Park, 215122, Suzhou China	
Tested by (name, function, signature) .... :	Zack Wu, Project Handler	Zack Wu
Approved by (name, function, signature) .. :	Ivan Wan, Reviewer	Ivan Wan
[ ] **Testing procedure: WMT:**		
Testing location/ address .... :		
Tested by (name, function, signature) .... :		
Approved by (name, function, signature) .. :		

List of Attachments (including a total number of pages in each attachment):

Refer to Appendix A of this report. All attachments are included within this report.

Summary of testing:

Tests performed (name of test and test clause):	**Testing location:**
Refer to the Test List in Appendix D of this report if testing was performed as part of this evaluation.	*Refer to the Test List in Appendix D of this report if testing was performed as part of this evaluation.*

Summary of compliance with National Differences (List of countries addressed):

List of countries addressed: United States of America, Canada

[X] The product fulfils the requirements of 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.

Statement concerning the uncertainty of the measurement systems used for the tests
(may be required by the product standard or client)

[ ] **Internal procedure used for type testing through which traceability of the measuring uncertainty has been established:**

Procedure number, issue date and title:

Calculations leading to the reported values are on file with the NCB and testing laboratory that conducted the testing.

[X] **Statement not required by the standard used for type testing**

(Note: When IEC or ISO standard requires a statement concerning the uncertainty of the measurement systems used for tests, this should be reported above. The informative text in parenthesis should be delete in both cases after selecting the applicable option)

Copy of marking plate

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

Refer to the enclosure(s) titled Marking Label in the Enclosures section in Appendix A of this report for a copy.

Test item particulars ....:	
Classification of Installation and Use:	Component for building-in
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
Supply Connection:	N/A (to be considered in end-use product)
Accessories and detachable parts included:	None
Other Options Include:	None
Possible test case verdicts:	
- test case does not apply to the test object ....:	N/A
- test object does meet the requirement ....:	P (Pass)
- test object was not evaluated for the requirement........... :	N/E (collateral standards only)
- test object does not meet the requirement ....:	F (Fail)
Abbreviations used in the report:	
- normal condition ....: N.C.	- single fault condition.................: S.F.C.
- means of Operator protection ....: MOOP	- means of Patient protection ....: MOPP
Testing ....:	
Date of receipt of test item ....:	2024-09-14
Date(s) of performance of tests ....:	2024-09-19
General remarks:	
"(See Enclosure #)" refers to additional information appended to the report. "(See appended table)" refers to a table appended to the report. **Throughout this report a ☐ comma / ☒ point is used as the decimal separator.**	
Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:	
The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided ....:	Yes
When differences exist; they shall be identified in the General product information section.	
Name and address of factory (ies)......................... :	Same as Applicant TDK-LAMBDA MALAYSIA SDN BHD PLO33 KAWASAN PERINDUSTRIAN SENAI SENAI JOHOR 81400 MY
General product information and other remarks:	

Report Summary

All applicable tests according to the referenced standard(s) have been carried out.

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

For project 4791516537 E508584-D1008-1/A1/C0-UL
Amendment 1:
1. Correct the typo error from ‘B825’ to ‘T825’ for Primary Terminal Block (TB1) in the List of critical components. See Table 8.10 for details.
2. Add a new model ‘T302 series’ for Primary Terminal Block (TB1), which is identical to the previous model except the appearance.See Table 8.10 for details.

Technical Considerations

- The product was investigated to the following standards:

  Main Standard(s):

  IEC 60601-1:2005, AMD1:2012, AMD2:2020

  From Country Differences:

  - United States of America: AAMI ES60601-1:2005,ES60601-1:2005/AMD1 1:2012 , ES60601-1:2005/AMD2:2021

  - Canada: 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

  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.

  The maximum specified operational ambient temperature is 70 °C. For derating curve, see Enclosure ID Miscellaneous-(002).

Engineering Conditions of Acceptability

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

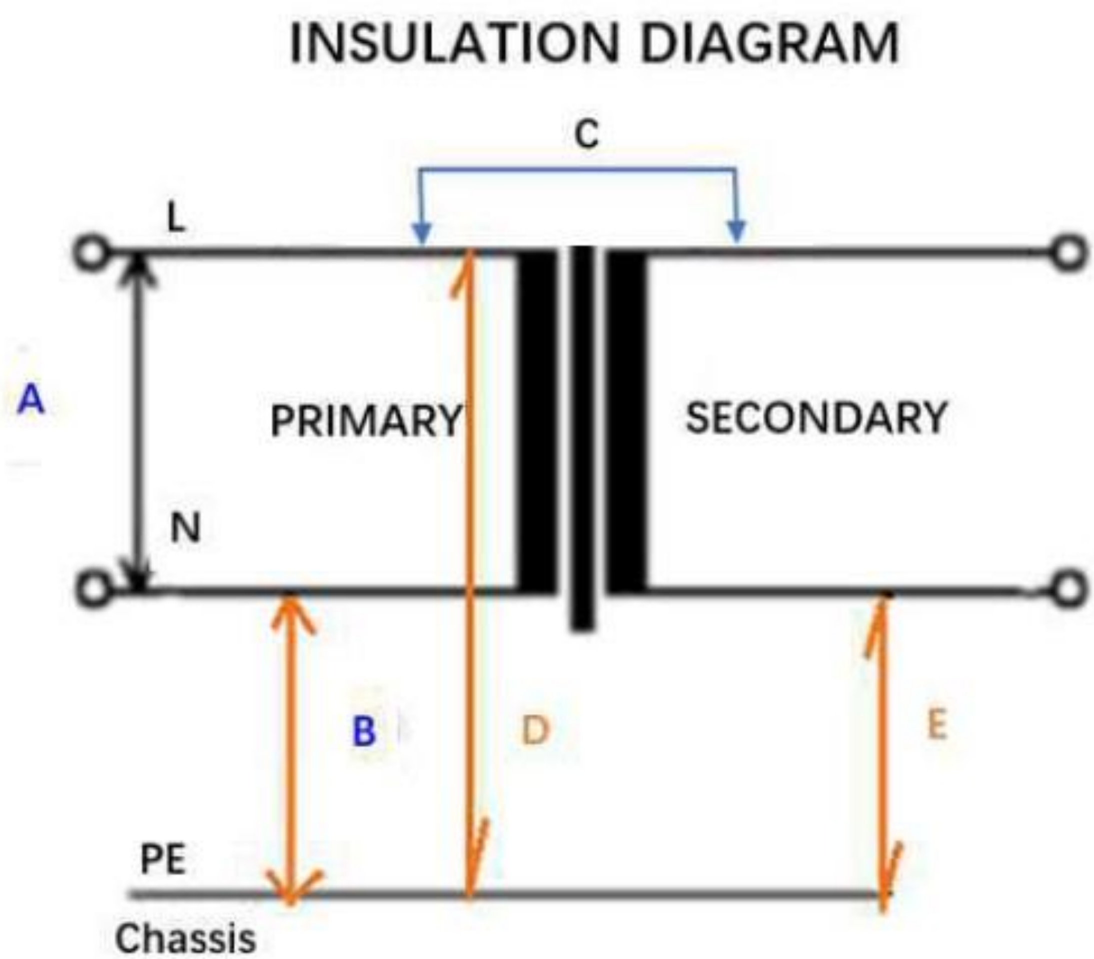
test corner as part of the power supply.
For Power Supplies with No RM or Units without Cleaning/Disinfection Methods: End product to determine the acceptability of risk in conjunction to the Cleaning and Disinfection Methods as part of the power supply.
For Power Supplies with No RM or Units with Liquids: 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.

Report Modifications

Date Modified *(Year-Month-Day)*	Modifications Made (include Report Reference Number)	Modified By
2024-01-09	Original report	Zack Wu
2024-10-28	For project 4791516537 E508584-D1008-1/A1/C0-UL Amendment 1: 1. Correct the typo error from ‘B825’ to ‘T825’ for Primary Terminal Block (TB1) in the List of critical components. See Table 8.10 for details. 2. Add a new model ‘T302 series’ for Primary Terminal Block (TB1), which is identical to the previous model except the appearance.See Table 8.10 for details.	Zack Wu

Insulation Diagram - (001) Insulation Diagram

Insulation Diagram - (001) Insulation Diagram



IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

TABLE: INSULATION DIAGRAM										Pass
Pollution Degree:			**2**							-
Overvoltage category:			**II**							-
Altitude:			**5000 (m)**							-
Additional details on parts considered as applied parts:			**[X] None [ ] Areas: (See Clause 4.6 for details)**							-
Area	**Number and type of Means of Protection: MOOP, MOPP**	**CTI**	**Working Voltage**		**Required creepage (mm)**	**Required clearance (mm)**	**Measured creepage (mm)**	**Measured clearance (mm)**	**Remarks**	
			Vrms	**Vpk**						
A	1 MOOP	IIIb	240	340	2.6	3.0	4.9	4.9	L to N before fuse	
A	1 MOOP	IIIb	240	340	2.6	3.0	3.1	3.1	Primary traces under fuse	
B&D	1 MOPP	IIIb	240	340	4.0	3.3	4.9	4.9	L/N to GND	
B&D	1 MOPP	IIIb	240	340	4.0	3.3	5.3	5.3	Trace under YCap C2	
B&D	1 MOPP	IIIb	240	340	4.0	3.3	7.3	7.3	Trace under YCap C4/C5	
B&D	1 MOPP	IIIb	240	340	4.0	3.3	5.3	5.3	Trace under YCap C62	
B&D	1 MOPP	IIIb	240	340	4.0	3.3	6.7	6.7	Trace under YCap C53/C54	
C	2 MOPP	IIIb	240	340	8.0	6.5	8.5	8.5	Trace under opto-couplers	
C	2 MOPP	IIIb	271	460	12.0	9.1	30.0	30.0	Primary pin to Secondary pin under under T1 (Ext.)	
C	2 MOPP	IIIb	271	460	12.0	9.1	12.6	12.6	Primary to secondary of T1(Int.)	
C	2 MOPP	IIIb	364	584	12.0	9.1	12.5	12.5	Primary pin to Secondary pin under under T2 (Ext.)	
C	2 MOPP	IIIb	364	584	12.0	9.1	TIW*	TIW*	Primary to secondary of T2 (Int.)	
E	1 MOPP	IIIb	240**	340**	4.0	3.3	4.5	4.5	Secondary circuits to GND	

Supplementary Information:
For clearance and creepage did not describe as above are far larger than limit.For all modules.*The approved TIW used in secondary side of the T2. See table 8.10 for details.**Required by customer.
INSULATION DIAGRAM CONVENTIONS and GUIDANCE:
A measured value must be provided in the value columns for the device under evaluation. The symbol > (greater than sign) must not be used. Switch-mode power supplies must be re-evaluated in the device under evaluation therefore N/A must not be used with a generic statement that the component is certified. Insulation diagram is a

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:

- All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.
- Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional
- Applied parts are extended beyond the equipment enclosure and terminated with an arrow.
- Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.