Underwriters Laboratories (UL LLC)
Safety Certification Report

Model:	Series: Alpha 800, Alpha 800W. Models: CA800 (followed by various letters and numbers as defined in the model differences) Series: Alpha 1000, Alpha 1000W. Models: CA1000 (followed by various letters and numbers as defined in the model differences), CA1250 12C_MF_PP 12F_PP 12F_PP 12F_PP, CA1250 12C_MF 12FF 12FF 12FF
Device Description:	Switch Mode Power Supply
Applicant:	TDK-Lambda UK Ltd Kingsley Avenue, Ilfracombe Devon, EX34 8ES United Kingdom
Manufacturer:	Same as Applicant
Manufacturing Facility(ies):	Same as Applicant Panyu Trio Microtronic Co. Ltd, Shiji Industrial Estate, Dongyong, Nansha Guangzhou, Guangdong China
Report No.:	E349607-D1023-1/A0/C0-UL
Report (Re)Issue Date:	2023-12-11
Base Standard(s):	ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14
Additional Standards:	National standard JIS T 0601-1:2023
Report Types:	This report consists of the following report types: - [Yes] US Certification (UL Recognition) - [Yes] CAN Certification (cUL Recognition)

This report covers the Safety evaluation of the referenced model(s) according to the standard(s) specified above.

Table of Contents

Report Modifications Summary

The following changes were made to this report. If none listed in the below table, this report is the originally issued report.

The following scheme is used throughout this report to reflect the **Report No.**:

(File No.) – (Report Ref. No.) – (x) / A(y) / C(z) – YYY, where:
(x) = Report (Re)Issue No.
(y) = Amendment No.
(z) = Correction No.
YYY = Report Type (UL/CB/IEC)

*NOTE: The **CB Certificate** may not be updated for report corrections that don't affect the CB Certificate contents; therefore if this report includes a correction number (z), it may not be reflected in the CB Certificate.*

Date Modified *(Year-Month-Day)*	Modifications Made (include Report Reference Number)	Modified By
2023-12-11	Reissue 1: This report is an original issue, based on CBTR E349607-D8, CBTC DK-45833-M1-UL issued on 2023-01-18. Report was issued to include following changes: - update to IEC 60601-1:2005, AMD1:2012, AMD2:2020; - update to 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; - addition of interchangeable alternative option to component C105 X Capacitors - addition of interchangeable alternative option to Connector Housings - correction of LoCC entries for T202, T302 transformers - correction of LoCC entries for secondary windings - correction of LoCC entry for U1 optocouplers Based on the previously conducted testing and the review of product technical documentation including photos, schematics, wiring diagrams and similar, has been determined that the product continues to comply with the standard.	Paweł Wasiak

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 .....:	E349607-D1023-1/A0/C0-UL
Date of issue .....:	2023-12-11
Total number of pages.....:	222
Name of Testing Laboratory preparing the Report.....:	UL International Germany GmbH Admiral-Rosendahl-Strasse 23, Zeppelinheim 63263 Neu-Isenburg , Germany
Applicant's name.....:	TDK-Lambda UK Ltd
Address .....:	Kingsley Avenue, Ilfracombe Devon, EX34 8ES United Kingdom
Test specification:	
Standard .....:	IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
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.....:	2022-05-13
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.....:	Switch Mode Power Supply
Trade Mark(s) .....:	-
Manufacturer .....:	Same as Applicant
Model/Type reference.....:	Series: Alpha 800, Alpha 800W. Models: CA800 (followed by various letters and numbers as defined in the model differences) Series: Alpha 1000, Alpha 1000W. Models: CA1000 (followed by various letters and numbers as defined in the model differences), CA1250 12C_MF_PP 12F_PP 12F_PP 12F_PP, CA1250 12C_MF 12FF 12FF 12FF
Ratings.....:	94.5 Vac to 240 Vac, (85-264Vac max. tolerance), 16A, 47-63 Hz, Class I

Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):

[X]	**UL/DAP Testing Laboratory:**		
Testing location/ address ..... :		UL International Germany GmbH Admiral-Rosendahl-Strasse 23, Zeppelinheim 63263 Neu-Isenburg , Germany	
Tested by (name, function, signature) ..... :		Paweł Wasiak, project handler	Paweł Wasiak
Approved by (name, function, signature) .. :		Grzegorz Kowalski, reviewer	Kowalski Grzegorz
[ ]	**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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020.

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:	Built-in
Supply Connection:	To be determined in end product
Device type (component/sub-assembly/ equipment/ system):	Component switch mode power supply
Intended use (Including type of patient, application location):	To provide DC power for electronic circuits with medical equipment
Mode of Operation:	Continuous
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 .....:	2015-02-04 to 2015-02-17, 2019-06-13 to 2020-09-03
Date(s) of performance of tests .....:	2015-02-18 to 2015-02-19, 2022-07-28
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 Panyu Trio Microtronic Co. Ltd, Shiji Industrial Estate, Dongyong, Nansha Guangzhou, Guangdong China
General product information and other remarks:	

Report Summary

Please refer to modification summary table in GPI section for more details

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

Product Description

The subject units are switch mode power supply sub-assemblies incorporating semiconductor components. They are provided with isolating transformers and associated circuitry mounted on printed wiring boards, in addition to input connectors for connection to mating connectors or wiring within the end use equipment.

Model Differences

See attachment Model Differences

Additional Information

N/A

Technical Considerations

- The product was investigated to the following standards:

  Main Standard(s):

  IEC 60601-1:2005+A1:2012

  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:

  National standard JIS T 0601-1:2023

- The following additional investigations were conducted: -
- 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)
- The following accessories were investigated for use with the product: None
- No Other Considerations

Engineering Conditions of Acceptability

When installed in an end-product, consideration must be given to the following:

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:

• These units are forced-air cooled. They require a minimum of 50 mm clearance in the vicinity of the ventilation holes. Whilst relatively orientation insensitive, operation of these units when mounted vertically with air flow in a downward direction is affected by convection acting against the cooling airflow, and results in slightly hotter temperatures than if operated in the horizontal position. As a consequence of this, heating tests were carried out in the vertical orientation with airflow downwards to give the worst case temperatures, unless otherwise stated.

• A fire, electrical and mechanical enclosure is required for this equipment.

• Additional fusing may be required in the end product to meet the requirement of Cl. 8.11.5, Mains

fuses and Over Current Release. The product is only provided and tested with a single fuse.
• Consideration should be given to measuring the temperature on power electronic components and transformer windings when the power supply is installed in the end-use equipment. The end-use product shall ensure that the power supply is used within its ratings
• The output circuits have not been evaluated for direct patient connection (Type B, BF or CF).
• The input/output connectors are not acceptable for field connections, they are only intended for factory wiring inside the end-use product.
• The component shall be installed in compliance with the enclosure, mounting, marking, spacing, and separation requirements of the end use application
• Power supply provides the following MOOP (means of operator protection): 2 MOOP based upon a working voltage 329 Vrms, 652 Vpk between Primary to Secondary, 1 MOOP based upon a working voltage 284 Vrms, 384Vpk between Primary and Earth
• Temperature, Leakage Current, Protective Earthing, Dielectric Voltage Withstand, and Interruption of the Power Supply tests shall be considered as part of the end product evaluation.
• Proper bonding to the end-product main protective earthing termination is required.
• These products were considered to be a component part of a larger piece of Class 1 equipment. Full compliance with the standards will therefore depend on the installation in the final application.
• The product was submitted and tested for use at the manufacturer's recommended ambient temperature (Tma) of 50°C
• Magnetic devices Flyback trx T4/T1 and T202, T302 employ a Class F (155°C) or higher insulation system
• The PWB is rated 130°C
• The products were tested on a 20A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary
• Leakage current measurements with non-frequency weighted measuring device shall be performed during end product evaluation.
• End product Risk Management Process to include consideration of requirements specific to the Power Supply.
• End product Risk Management Process to consider the need for simultaneous fault condition testing.
• End product Risk Management Process to consider the need for different orientations of installation during testing.
• End product to determine the acceptability of risk in conjunction to insulation to resistance to heat, moisture, and dielectric strength.
• End product to determine the acceptability of risk in conjunction to the movement of components as part of the power supply.
• End product to determine the acceptability of risk in conjunction to the movement of conductors as part of the power supply.
• 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.
• 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.
• 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
□ Scope of Power Supply evaluation defers the following clauses to be determined as part of the end product: Clause 7.5 (Safety Signs), Clause 7.9 (Accompanying Documents), Clause 9 (ME Hazard), Clause 10 (Radiation), Clause 14 (PEMS), Clause 16 (ME Systems)
□ Scope of Power Supply evaluation excludes the following: Patient applied parts clauses: 4.6, 7.2.10, 8.3, 8.5.2, 8.5.5, 8.7.4.7-8.7.4.9, 8.9.1.15 Battery related clauses: 7.3.3, 15.4.3 Hand Control related clauses: 8.10.4 Oxygen related clauses: 11.2.2 Fluids related clauses: 11.6.2 – 11.6.4 Sterilization clause: 11.6.7 Biocompatibility Clause: 11.7 (ISO 10993) Motor related clauses: 13.2.13.3, 13.4 Heating Elements related clause: 13.2 Flammable Anaesthetic Mixtures Protection: Annex G

Report Modifications

Date Modified *(Year-Month-Day)*	Modifications Made (include Report Reference Number)	Modified By
2023-12-11	Reissue 1:	Paweł Wasiak

	This report is an original issue, based on CBTR E349607-D8, CBTC DK-45833-M1-UL issued on 2023-01-18. Report was issued to include following changes: - update to IEC 60601-1:2005, AMD1:2012, AMD2:2020; - update to 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; - addition of interchangeable alternative option to component C105 X Capacitors - addition of interchangeable alternative option to Connector Housings - correction of LoCC entries for T202, T302 transformers - correction of LoCC entries for secondary windings - correction of LoCC entry for U1 optocouplers Based on the previously conducted testing and the review of product technical documentation including photos, schematics, wiring diagrams and similar, has been determined that the product continues to comply with the standard.	