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-D1027-1/A0/C0-CB
Date of issue .....:	2024-01-09
Total number of pages.....:	187
Name of Testing Laboratory preparing the Report.....:	UL International Polska Sp. z o.o. Równoległa 4 PL-02-235 Warszawa Poland
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 .....:	CB Scheme
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

This report is not valid as a CB Test Report unless signed by an approved IECEE Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

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 supplies
Trade Mark(s) .....:	Trademark image(s): TDK·Lambda
Manufacturer .....:	Same as Applicant
Model/Type reference.....:	CUS150M (may be prefixed and followed by alphanumeric characters - See model differences section for details of nomenclature). CUS100ME (may be prefixed and followed by alphanumeric characters - See model differences section for details of nomenclature). KCUS100ME-32/0001# (where # can be any letter or character indicating non-safety related changes). TC40000750-## (where ## is for a revision only and can be any number - See model differences section for details of nomenclature Non-Standard CUS150M-18)
Ratings.....:	Input: CUS150M-xxVx/yyyy 100-240Vac; 47-63Hz; 2.2Arms Max. CUS100ME-xxVx/yyyy 100-240Vac; 47-63Hz; 1.4Arms Max. KCUS100ME-32/0001# 100-240Vac +10%/-10%; 47-63Hz; 1.4Arms Max. TC40000750-## 100-240Vac; 47-63Hz, 2.2Arms Max Output: CUS100ME-12/yyyy output: 12-13.2Vdc 8.33A CUS100ME-15/yyyy output: 15-16.5Vdc 6.66A CUS100ME-18/yyyy output: 18-19.8Vdc 5.55A CUS100ME-24/yyyy output: 24-26.4Vdc 4.16A CUS100ME-28/yyyy output: 28-30.8Vdc 3.57A CUS100ME-36/yyyy output: 36-39.6Vdc 2.77A CUS100ME-48/yyyy output: 48-50Vdc 2.08A KCUS100ME-32/0001# output: 32.2Vdc 3.11A CUS150M-12/yyyy output: 12-13.2Vdc 12.5A CUS150M-15/yyyy output: 15-16.5Vdc 10A CUS150M-18/yyyy output: 18-19.8Vdc 8.33A CUS150M-24/yyyy output: 24-26.4Vdc 6.25A CUS150M-28/yyyy output: 28-30.8Vdc 5.4A CUS150M-36/yyyy output: 36-39.6Vdc 4.2A CUS150M-48/yyyy output: 48-50Vdc 3.125A TC40000750-## Output: 18Vdc 6.66A

	Each output has a range shown in the table above which is factory configurable only. For further details please see model differences section.

Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):			
[X]	**CB Testing Laboratory:**		
Testing location/ address ..... :		UL International Polska Sp. z o.o. Równoległa 4 PL-02-235 Warszawa Poland	
Tested by (name, function, signature) ..... :		Maggie Chiu, Project Handler	Maggie Chiu
Approved by (name, function, signature) .. :		Krzysztof Wasilewski, Reviewer	Krzysztof Wasilewski
[ ]	**Testing procedure: CTF Stage 1:**		
Testing location/ address ..... :			
Tested by (name, function, signature) ..... :			
Approved by (name, function, signature) .. :			
[ ]	**Testing procedure: CTF Stage 2:**		
Testing location/ address ..... :			
Tested by (name, function, signature) ..... :			
Witnessed by (name, function, signature) . :			
Approved by (name, function, signature) .. :			
[X]	**Testing procedure: CTF Stage 3:**		
[ ]	**Testing procedure: CTF Stage 4:**		
Testing location/ address ..... :		TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE EX34 8ES UNITED KINGDOM	
Tested by (name, function, signature) ..... :		Mark Gisbey (Tester)	See original test report for signatures.
Witnessed by (name, function, signature) . :		Kamil Janeczek (Project Handler)	See original test report for signatures.

Approved by (name, function, signature) .. :	Tracy Burgess (Reviewer)	See original test report for signatures.
Supervised by (name, function, signature) :	Krzysztof Wasilewski (Project Reviewer)	See original test report for signatures.

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 B of this report if testing was performed as part of this evaluation.	*Refer to the Test List in Appendix B 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 part of host equipment
Supply Connection:	Connection to Mains via host equipment
Device type (component/sub-assembly/ equipment/ system):	Component Switch Mode Power Supply
Intended use (Including type of patient, application location):	To supply regulated power
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 .....:	2017-01-12, 2017-01-19, 2017-01-27; 2017-07-11; 2018-01-03, 2018-01-12, 2018-01-15; 2020-06-10; 2023-02-13
Date(s) of performance of tests .....:	2017-02-17 to 2017-02-28, 2017-03-3 to 2017-03-06, 2017-04-04; 2017-07-20; 2018-02-22 to 2018-03-14; 2020-06-12; 2023-01-05 to 2023-05-30
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)..... :	TDK-Lambda UK Ltd Kingsley Avenue, Ilfracombe Devon, EX34 8ES UNITED KINGDOM PANYU TRIO MICROTRONICS CO. LTD SHIJI INDUSTRIAL ESTATE DONGYONG, NANSHA, GUANGZHOU GUANGDONG CHINA TDK-Lambda Malaysia Sdn. Bhd.

Lot 2 & 3, Batu 9 3/4, Kawasan Perindustrian
Bandar Baru Jaya Gading
26070 Kuantan, Pahang Malaysia

General product information and other remarks:

Report Summary

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

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

Product Description

The product is a power supply for building in to end equipment. It is available as open frame, U chassis, U chassis and lid, Base plate and with a top fan version (CUS150M model only).

The power supply can be used as either a Class I or a Class II construction except for KCUS100ME-32/0001# which is a Class II only.

- For Class I construction, the power supply will need to be reliably earthed, professionally installed and fixed with suitable, metal screws.
-For Class II construction no earthing connection is required. The power supply needs to be fixed so that it is insulated from any unearthed accessible conductive part by reinforced insulation.

The power supply provides two fuses for input protection. One in the Live line and one in the Neutral line. Option E uses one fuse only. This is fitted in the live line only.

The power supply can be forced air (top fan or customer air), convection or conduction cooled. Due to the fact that air flow for cooling depends on end product use, only convection cooling and top fan configurations were considered during temperature measurement.

The component temperatures listed in the additional information shall not be exceeded.

Model Differences

The CUS has two ranges of 100W and 150W each with seven nominal output voltages of 12, 15, 18, 24, 28, 36 and 48 Volt. Each output has a range shown in the table below which is factory configurable only.

CUS models as described below:

Units may be marked with a Product Code: CUSZ-xxVx/yyyy where Z is 100ME or 150M and x may be any number of numbers or left blank to indicate the output voltage. V represents a decimal place when required or can be left blank. y can be blank or any number of numbers or letters (excluding M, E, U, A, F, B, H) when indicating non-safety related model differences. y can be M, E, U, A, F, B when indicating the standard options as listed below.
Unit Product Code may be prefixed by K, SP # and/or NS # followed by / or - (where # may be any number of characters indicating non-safety related model differences).

Unit Product Code:
CUSZ-xxVx/yyyy

Where:
Z = 150M for 150W model, 100ME for 100W model
xxVx = Channel 1 output voltage from within the output voltage adjustment range from the Output Parameters Tables below.
yyyy = Unit options from list of standard unit options below, or non-safety related model differences:
/M = Molex connectors
/E = Single fuse in the live line

/U = U chassis
/A = Cover and U chassis
/F = Top fan, cover and U chassis (CUS150M model only)
/B = Baseplate

Non standards
KCUSZ-xxVx-yyyy/H

Where:
Z = 100ME for 100W model
xxVx = Channel 1 output voltage from within the output voltage adjustment range from the Output Parameters Table below.
yyyy = Unit options from list of standard unit options below, or non-safety related model differences
/M = Molex connectors
/E = Single fuse in the live line
/U = U chassis
/A = Cover and U chassis
/F = Top fan, cover and U chassis (CUS150M model only)
/B = Baseplate
Followed by
/H = alternate link wire and discharge resistors

KCUS100ME-32/0001# is electrically identical to CUS100ME series except for the following:
- model designation
- Input tolerances (see Ratings for details).
- Class II only.
- output ratings
- Input (J1)/Output (J100) connectors are placed on the underside of the PCB and J2 not fitted.

TC40000750-## is a non-standard model of CUS150M-18 but providing 120W output only, where ## is for a revision only and can be any number for internal and marketing purposes only.
It uses a fully approved CUS150M-18 unit mounted on a heatsink and has IEC AC inlet, input/output PCBs.

Input Parameters
Nominal input voltage: 100 - 240Vac,
Input voltage range : 85 - 264Vac,
Input frequency range: 47 - 63Hz,
Maximum input current: 2.2A rms (CUS150M), 1.4A rms (CUS100ME)

All ratings apply for ambient temperatures up to 50°C. (see Variations and Limitations below)
Output power is reduced linearly by 10% for input voltages from 90 to 85Vac

Output Parameters

There are seven CUS150M and CUS100ME standard models as shown in the tables below. All of these models may be fan(CUS150M model only), forced air, conduction or convection cooled. The output parameters are shown in the tables below.
Outputs are not user adjustable but can be factory set.

CUS150M

	Vout	*Fan	Max	Max		*Fan Output ratings	
Model	Range (V)	Vnom (V)	Iout (A)	Pout (W)	Inom (A)	Pnom (W)	
12	12-13.2	11.6	12.5	150	0.5	5.8	
15	15-16.5	9.8	10	150	0.5	4.9	
18	18-19.8	11.6	8.33	150	0.5	5.8	
24	24-26.4	11.6	6.25	150	0.5	5.8	
28	28-30.8	10.8	5.4	150	0.5	5.4	
36	36-39.6	11.6	4.2	150	0.5	5.8	
48	48-50	11.6	3.125	150	0.5	5.8	

* Fan output tracks Vout Range

Variation and Limitations:

Customer Forced Air Cooling max ambient 85°C (note 1)
Convection and conduction/cold plate Cooling (U chassis with lid-Option A) max ambient 75°C (note 1)
Convection and conduction/cold plate Cooling (U chassis and open frame) max ambient 80°C (note 1)
Fan supplied ratings/Option F max ambient 70°C, from 50°C to 70°C the output power is de-rated by 0.5°C per watt
Note 1. Maximum output power and current ratings are dependent on the ambient used in the end equipment.

CUS100M

Model	Vout Range (V)	Max Iout (A)	Max Pout (W)
12	12-13.2	8.33	100
15	15-16.5	6.66	100
18	18-19.8	5.55	100
24	24-26.4	4.16	100
28	28-30.8	3.57	100
36	36-39.6	2.77	100
48	48-50	2.08	100

Variation and Limitations:

Customer Forced Air Cooling max ambient 85°C (note 1)
Convection and conduction/cold plate Cooling (U chassis with lid-Option A) max ambient 75°C (note 1)
Convection and conduction/cold plate Cooling (U chassis and open frame) max ambient 80°C (note 1)
Note 1. Maximum output power and current ratings are dependent on the ambient used in the end equipment.

Series connection
It is permitted to connect output of maximum two units in series. Doing so changes the working voltages as shown in the test tables. This is only applicable to Class I units.

Additional Information

Cooling for units with forced air cooling (Except option F)

The product can also operate at input voltage lowered to 85Vac with linear output de-rating to -10%.

The following method must be used for determining the safe operation of PSUs.
The components listed in the following table must not exceed the temperatures given. To determine the component temperatures the heating tests must be conducted in accordance with the requirements of the standard in question. Consideration should also be given to the requirements of other safety standards.
Test requirements include: PSU to be fitted in its end-use equipment and operated under the most adverse conditions permitted in the end-use equipment handbook/specification and which will result in the highest temperatures in the PSU. To determine the most adverse conditions consideration should be given to the end use equipment maximum operating ambient, the PSU loading and input voltage, ventilation, end use equipment orientation, the position of doors & covers, etc. Temperatures should be monitored using type K fine wire thermocouples (secured with cyanoacrylate adhesive or similar) placed on the hottest part of the component (out of any direct airflow) and the equipment should be run until all temperatures have stabilized.

CUS150M Cooling for Unit Temperature Table:

Circuit Ref.	Description Max.	Temperature (°C)
L1	Common Mode Choke	110 (130)
L2	PFC choke 125	(130)
L3	Differential mode choke	125 (130)

C1	Film capacitor	105
C2, C110	Electrolytic Capacitors	86 (105)
C6, C102, C104, C105	Electrolytic Capacitors	92 (105)
C3	X Capacitor	100
C5, C100, C101, C103,	Y Capacitors	105
TX100	Transformer Winding	110
XU101, XU102	Opto-Coupler 100	(110)
XD8	Diode	130
J1	Input Connector	105
J100	Output Connector	105

CUS100ME Cooling for Unit Temperature Table:

Circuit Ref.	Description Max.	Temperature(°C)
L1	Common Mode Choke	110 (130)
L2	PFC choke	125 (130)
L3	Differential mode choke	125 (130)
C1	Film capacitor	105
C2	Electrolytic Capacitors	90 (105)
C104, C105	Electrolytic Capacitors	92 (105)
C6, C102	Electrolytic Capacitors	93 (105)
C3	X Capacitor	100
C5, C100, C101, C103,	Y Capacitors	105
TX100	Transformer Winding	110
XU101, XU102	Opto-Coupler	100 (110)
XD8	Diode	130
J1	Input Connector	105
J100	Output Connector	105

Higher temperature limits (in brackets) may be used but product life may be reduced.

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: Biocompatibility, PESS, EMC, Annex Z of EN standards for compliance with the MDD, Risk Management
- The following accessories were investigated for use with the product: n/a
- No Other Considerations

Engineering Conditions of Acceptability

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

The following production line tests are conducted for this product: Electric Strength, Earthing Continuity
The following production line tests are not conducted for this product and it shall be considered in end-product: Patient Circuit Dielectric Voltage-Withstand Test.
The following output terminals were referenced to earth during performance testing: All outputs and their return lines individually referenced to earth to obtain maximum working voltage
The power supply terminals and/or connectors are: not investigated for field wiring
The maximum investigated branch circuit rating is: 20A
The investigated pollution degree is: II
Proper bonding to the end product main protective earthing termination is: required in a Class I application
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): TX100 (class B)
The following end-product enclosures are required: Mechanical, Fire, Electrical
Earth and touch leakage current measurements were done with no load and shall be re-considered in end-use application.
EMC compliance has not been verified nor has it been taken into consideration. An accredited EMC Test Report will be required in conjunction with the Certification of the end product.
All models require component temperatures to be monitored as detailed in the additional information.
The end-product Dielectric Strength Test is to be based upon a maximum working voltage of: Primary-Secondary: 240 Vrms, 480 Vpk, Primary-Earthed Dead Metal: 350 Vrms,410 Vpk, Secondary outputs-Earthed Dead Metal: 240Vrms, 340Vpk.
For units connected in series (series connection of secondary outputs) the end-product Electric Strength Test is to be based upon a maximum working voltage of : Primary – Earthed Dead Metal: 480Vrms, 427.1Vpk; Primary-Secondary: 451Vrms, 510Vpk.
For units connected in series (series connection of secondary outputs) the following tests shall be considered in end-product: Earth Leakage Current, Voltage or Charge Limitation, Temperature Test.

Report Modifications

Date Modified *(Year-Month-Day)*	Modifications Made (include Report Reference Number)	Modified By
2024-01-09	This report is based on CBTR Ref. No. E349607-D1003-2/A2/C0, CBTC Ref. No. DK-98789-M2-UL, DK-98790-M2-UL, issued on 2023-10-19. It was modified to include the following: 1. Standards upgraded 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, IEC 60601-1:2005, AMD1:2012, AMD2:2020 2. TRF updated due to the standard upgrade. 3. Test Tables updated due to the standard upgrade. No testing was conducted under this investigation. All required tests were carried out under the original investigation. The test sample received dates and the test dates are from the original report. Per the previously conducted testing and the review of product technical documentation including photos, schematics, wiring diagrams and similar, it has been determined that the product continues to comply with the standard.	Maggie Chiu