Underwriters Laboratories (UL LLC)
Safety Report

Model:	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)
Device Description:	Switch-mode power supplies
Applicant:	TDK-Lambda UK Ltd Kingsley Avenue, Ilfracombe Devon, EX34 8ES UNITED KINGDOM
Manufacturer:	Same as Applicant
Manufacturing Facility(ies):	TDK-Lambda UK Ltd Kingsley Avenue, Ilfracombe Devon, EX34 8ES UNITED KINGDOM PANYU TRIO MICROTRONIC CO. LTD SHIJI INDUSTRIAL ESTATE DONGYONG, NANSHA, GUANGZHOU GUANGDONG CHINA
Report No.:	E349607-D1003-1/A2/C0-ULCB
Report (Re)Issue Date:	2017-04-14; 2017-09-25 (A1); 2018-03-21 (A2)
Base Standard(s):	ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14, IEC 60601-1 Edition 3.1 (2012)
Additional Standards:	EN 60601-1:2006/A1:2013, KS C IEC 60601-1, ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14, BS EN 60601:2006 A1, SS-EN 60601-1:2006+A11:2011+A1:2013+AC1:2014+A12:2014
Report Types:	This report consists of the following report types: [Yes] US Certification (UL Recognition) [Yes] CAN Certification (cUL Recognition) [Yes] CB Report & Certificate [No] IEC/EN Informative Report

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

The **CB Certificate** is provided as a separate enclosure to this report and not provided in the body of this report.

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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
2017-08-29	Amendment 1: measurements of earth leakage current and touch current repeated per client's request (E349607-D1003-1/A1/C0-ULCB)	Hubert Koszewski
2018-03-21	Amendment 2: Technical amendment was issued in order to add CUS100ME, CUS150M-15, CUS150M-18, CUS150M-28, CUS150M-36 and DC rated version of CUS150M series. Due to the modification following report sections were modified: general product information, insulation table, clause list and test tables. Only limited testing was considered necessary due to similarity to previously evaluated construction. This amendment shall be read in conjunction with the Original CB Report No.E349607-D1003-1/A0/C0-ULCB and Amendment-1 issue 2017-08-29.	Krzysztof Wasilewski

Test Report issued under the responsibility of:

IEC 60601-1
Medical electrical equipment
Part 1: General requirements for basic safety and essential performance

Report Reference No. ..... :	E349607-D1003-1/A2/C0-ULCB
Date of issue ..... :	2017-04-14; 2017-09-25 (A1); 2018-03-21 (A2)
Total number of pages ..... :	177
CB Testing Laboratory ..... :	UL International Polska Sp. z o.o. Aleja Krakowska 81 05-090 Sekocin Nowy Warszawy POLAND
Address ..... :	
Applicant's name ..... :	TDK-Lambda UK Ltd
Address ..... :	Kingsley Avenue, Ilfracombe Devon, EX34 8ES UNITED KINGDOM
Test specification:	
Standard ..... :	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)
Test procedure ..... :	CB Scheme
Non-standard test method..... :	N/A
Test Report Form No..... :	IEC60601_1K
Test Report Form Originator ..... :	UL(US)
Master TRF ..... :	2015-11

This report is not valid as a CB Test Report unless signed by an approved CB 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 CB testing laboratory. 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:	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)
Ratings:	Input: CUS150M-xxVx/yyyy 100-240Vac; 47-63Hz; 2.2Arms Max. CUS150MD-xxVx/yyyy 133-318Vdc, 1.8A CUS100ME-xxVx/yyyy 100-240Vac; 47-63Hz; 1.4Arms 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 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 Each output has a range shown in the table above which is factory configurable only. For further details please see model differences section.
Testing procedure and testing location:	

[X] CB Testing Laboratory:		
Testing location/ address:	UL International Polska Sp. z o.o. Aleja Krakowska 81 05-090 Sekocin Nowy Warszawy POLAND	
[ ] Associated CB Testing Laboratory:		
Testing location/ address:		
Tested by (name, function, signature):	Krzysztof Wasilewski, Project Handler	Krzysztof Wasilewski
Approved by (name, function, signature):	Bruno Motta, Reviewer	Bruno F. Motta
[ ] 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):		
[ ] Testing procedure: CTF Stage 3:		
[ ] Testing procedure: CTF Stage 4:		
Testing location/ address:		
Tested by (name, function, signature):		
Witnessed by (name, function, signature):		
Approved by (name, function, signature):		
Supervised 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.*
Summary of compliance with National Differences List of countries addressed: Austria, Korea, Republic of, USA, Canada, United Kingdom, Sweden [X] The product fulfils the requirements of IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint) .

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.

GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of Installation and Use:	Component part of 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
Supply Connection:	Connection to Mains via host equipment
Accessories and detachable parts included:	None
Other Options Include:	None
Testing	
Date of receipt of test item(s) .....:	2017-01-12, 2017-01-19, 2017-01-27; 2017-07-11 (A1); 2018-01-03, 2018-01-12, 2018-01-15 (A2)
Dates tests performed .....:	2017-02-17 to 2017-02-28, 2017-03-3 to 2017-03-06, 2017-04-04; 2017-07-20 (A1); 2018-02-22 to 2018-03-14 (A2)
Possible test case verdicts:	
- test case does not apply to the test object .....:	N/A
- test object does meet the requirement.....:	Pass (P)
- test object was not evaluated for the requirement ..... :	N/E
- test object does not meet the requirement.....:	Fail (F)
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
General remarks: Before starting to use the TRF please read carefully the 4 instructions pages at the end of the report on how to complete the new version “K” of TRF for IEC for 60601-1 3rd edition with Amendment 1. "(See Attachment #)" refers to additional information appended to the report. "(See appended table)" refers to a table appended to the report. The tests 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 testing laboratory. List of test equipment must be kept on file and available for review. Additional test data and/or information provided in the attachments to this report. Throughout this report a point is used as the decimal separator.	
Manufacturer’s Declaration per sub-clause 4.2.5 of IECEE 02:2012	
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 MICROTRONIC CO. LTD SHIJI INDUSTRIAL ESTATE DONGYONG, NANSHA, GUANGZHOU GUANGDONG CHINA

GENERAL PRODUCT INFORMATION:

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 CUS150M 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.

The power supply can be used as either a Class I or a Class II construction.

- 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 left 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 (may be followed by 'D' for DC input), 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

Input Parameters

Nominal input voltage:	100 - 240Vac,	133 - 318Vdc*
Input voltage range :	85 - 264Vac,	120 - 350Vdc*
Input frequency range:	47 - 63Hz,	DC*
Maximum input current:	2.2A rms (CUS150M), 1.4A rms (CUS100ME)	1.8A*

* 60601-1 2nd ed, 300Vdc input max. DC rating applies for CUS150M family only.

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.

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):

  ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14, IEC 60601-1 Edition 3.1 (2012)

  From Country Differences:

  - Austria: EN 60601-1:2006/A1:2013
  - Korea, Republic of: KS C IEC 60601-1
  - USA: ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
  - Canada: CSA CAN/CSA-C22.2 NO. 60601-1:14
  - United Kingdom: BS EN 60601:2006 A1
  - Sweden: SS-EN 60601-1:2006+A11:2011+A1:2013+AC1:2014+A12:2014

  Additional Standards:

  EN 60601-1:2006/A1:2013, KS C IEC 60601-1, ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14, BS EN 60601:2006 A1, SS-EN 60601-1:2006+A11:2011+A1:2013+AC1:2014+A12:2014

- 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
- 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 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

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.

Report Modifications

Date Modified *(Year-Month-Day)*	Modifications Made (include Report Reference Number)	Modified By
2017-08-29	Amendment 1: measurements of earth leakage current and touch current repeated per client's request (E349607-D1003-1/A1/C0-ULCB)	Hubert Koszewski
2018-03-21	Amendment 2: Technical amendment was issued in order to add CUS100ME, CUS150M-15, CUS150M-18, CUS150M-28, CUS150M-36 and DC rated version of CUS150M series. Due to the modification following report sections were modified: general product information, insulation table, clause list and test tables. Only limited testing was considered necessary due to similarity to previously evaluated construction. This amendment shall be read in conjunction with the Original CB Report No.E349607-D1003-1/A0/C0-ULCB and Amendment-1 issue 2017-08-29.	Krzysztof Wasilewski