Test Report issued under the responsibility of:

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

Report Number. .....:	E349607-D1017-1/A2/C1-CB
Date of issue .....:	2021-10-26, 2021-11-12 (A0/C1), 2022-08-30(A1), 2024-03-26(A2)
Total number of pages.....:	401
Name of Testing Laboratory preparing the Report.....:	UL International Demko A/S Borupvang 5A, DK-2750 Ballerup, Denmark
Applicant's name.....:	TDK-Lambda UK Ltd
Address .....:	Kingsley Avenue Ilfracombe, EX34 8ES UNITED KINGDOM
Test specification:	
Standard.....:	IEC 60601-1:2005, AMD1:2012
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_1S
Test Report Form Originator.....:	UL(US)
Master TRF .....:	2020-12-17

If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed.

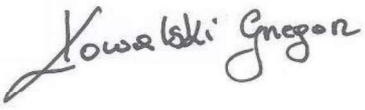
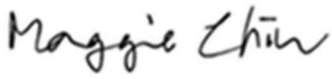
This report is not valid as a CB Test Report unless signed by an approved IECEE Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

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.....:	Component switch mode power supply
Trade Mark(s) .....:	Trademark image(s): TDK·Lambda
Manufacturer .....:	Same as Applicant
Model/Type reference.....:	(K)CUS250M-xxVx/yyyyyyy/(NNNNL), where N is a string of numbers which identifies the non-standard requirement and L is an optional letter, starting with 'A' which is incremented for any customer revisions. CUS250M-xxVx/yyyyyyy/(SPNN), where SP represents a sales code. NN may be any number of characters indicating non-safety related model differences. (CUS250M may be followed by suffix 'D' for DC Input) (Where xxVx = Channel 1 output voltage, may be 12V, 15V, 18V 24V, 28V, 36V, 48V. The letter "V" only applies to the non-standard output voltages. E.g. 12V6 to represent 12.6V. Where yyyyyyy = unit options such as case options (may be blank, U, A, F, or C), Connector options (may be blank or M), Fuse options (may be blank or E), signal, standby options (may be blank, G, J, or K), Leakage current options (may be blank or T), Output connector options (may be blank or L), Coating options (may be blank or P).) (See Model Differences section for more details)
Ratings.....:	100 – 240Vac nominal, 3.1A max, 47-63Hz 133 - 318Vdc nominal, 3.0A max (See model differences for details of ratings)

Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):			
[X]	**CB Testing Laboratory:**		
Testing location/ address ..... :		UL International Demko A/S Borupvang 5A, DK-2750 Ballerup, Denmark	
Tested by (name, function, signature) ..... :		Maggie Chiu, Project handler	Maggie Chiu
Approved by (name, function, signature) .. :		Grzegorz Kowalski, reviewer	Kowalski Grzegorz
[ ]	**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 ..... :		CTF3: TDK-Lambda UK Limited Kingsley Avenue Ilfracombe, EX34 8ES United Kingdom	
Tested by (name, function, signature) ..... :		K. Laffey (Product Safety Engineer), M. Carter (Product Safety Engineer), M. Gisbey (Junior Product Safety Engineer)	
Witnessed by (name, function, signature) . :		N/A	See GPI for details
Approved by (name, function, signature) .. :		Grzegorz Kowalski, reviewer	
Supervised by (name, function, signature) :		Maggie Chiu, project handler	

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: Republic of Korea, USA, Canada, United Kingdom (No National or Group Differences declared), Japan, Israel

[X] The product fulfils the requirements of KS C IEC 60601-1, 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, National standard JIS T 0601-1:2017 (IEC 60601-1:2005 + A1:2012(MOD)), SI 60601 Part 1 (2018-06).

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
Intended use (Including type of patient, application location):	To provide DC power for electronic circuit within 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 .....:	2021-01-19 to 2021-08-12, 2022-04-12, 2022-12-13, 2023-01-06, 2023-04-05, 2023-09-06, 2023-09-12, 2023-09-23
Date(s) of performance of tests .....:	2021-01-21 to 2021-09-02, 2022-04-13, 2023-04-26 to 2023-10-20, 2024-03-11 to 2024-03-13

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 Microtronics Co Ltd SHIJI INDUSTRIAL ESTATE DONGYONG NANSHA GUANGZHOU GUANGDONG 511453CN China

	TDK-LAMBDA MALAYSIA SDN BHD LOT 2 & 3, BATU 9 3/4 KAWASAN PERINDUSTRIAN BANDAR BARU JAYA GADING KUANTAN Pahang MY 26070 Malaysia TRIO-TRONICS (THAILAND) LTD 7/295 Mu. 6 Map Yang Phon Sub-District Pluak Daeng District Rayong Thailand

General product information and other remarks:

Report Summary

See report modification summary

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

Product Description

The CUS250M is an AC-DC switch mode power supply designed for building in to end equipment in either a class I or class II configuration. It is available in the following mechanical configurations:

- Standard model with integral metal baseplate,
- U channel,
- U channel with cover,
- U channel with cover and top fan
- Standard model with integral metal baseplate with M3 threaded inserts for underside mounting
- Custom baseplate / U chassis with alternate fixings / inserts

The unit is fitted with two fuses as standard with one fuse in the live line and one in the neutral line. Option E allows for a single fuse to be fitted in the live line.

The unit can be cooled via forced air (top fan and customer air versions), convection or conduction. All variants that are not supplied with a fan are dependent on the end equipment application and therefore testing must be carried out in the end equipment to ensure compliance with the stated component temperatures listed in the “Additional application considerations” section of this report.

For Class I construction, the power supply needs to be reliably earthed, professionally installed and fixed with suitable metal screws.

For Class II construction no earth connection is required however the power supply needs to be fixed so that it is insulated from any unearthed accessible conductive part by reinforced insulation.

For model CUS250M followed by suffix ‘D’ is available for DC Input and it is limited to altitude of 3000m

Model Differences

The CUS250M has a maximum rated power of 250W and has several nominal output voltages of 12Vdc, 15Vdc, 18Vdc, 24Vdc, 28Vdc, 36Vdc and 48Vdc.

Nomenclature
Unit Product Code: CUS250M-xxVx/yyyyyyy

CUS250M may be followed by ‘D’ for DC Input

Where: xxVx = Channel 1 output voltage from within the output voltage adjustment range from the “Output

Parameters" table below.

Where yyyyyyy = unit options from the list of standard options below

Case Options (all case options and metal base include gap pads)
Blank = Open frame (with integral metal baseplate)
U = U channel
A = U channel with cover
F = U channel, cover and top mounted fan
C = M3 inserts for underside mounting
N = Custom baseplate / U chassis with alternate fixings / Inserts

Connector Options:
Blank = JST connector
M = Molex type connector

Fuse Options:
Blank = Dual fuse (standard)
E = With single fuse in live line

Signal, Standby Options:
Blank = No option (fan supply is standard)
G = 5V, 0.1A standby supply, remote on/off (enable), DC_OK, AC_Fail
J = 5V, 0.1A standby supply, remote on/off (inhibit), DC_OK, AC_Fail
K = Remove fan supply (CH1 only)

Leakage Current Options:
Blank = Standard leakage (<150µA)
T = Reduced leakage current (<50µA)

Output Connector Options:
Blank = Screw terminal
L* = Custom option *can be any number denoting different connector type

Coating Options:
Blank = No coating
P = Protective coating

Example: CUS250M-24V5/UEP = 24.5V with U channel, JST connector, single fuse in the live line, no options, standard leakage and protective coating

Non-standard Models:

Unit product code may be prefixed with 'K' followed by any standard product code followed by /NNNNL where N is a string of numbers which identifies the non-standard requirement and L is an optional letter, starting with A which is incremented for any customer revision.

Example: KCUS250M-24/0001A

Unit product code may be suffixed by /NNNNL where N is a string of numbers which identifies the non-standard requirement. L is an optional letter, starting with 'A', which is incremented for any customer revision.

Example: CUS250M-24/0001A

Unit product code may be suffixed by SPNN (where NN may be any number of characters indicating non-safety related model differences) (SP represents a sales code).

Example: CUS250M-24/FE/SP01

Input Parameters
Nominal Input Voltage 100* – 240Vac, 133 - 318Vdc
Input Voltage Range 80** – 264Vac, 120 – 350Vdc
Input Frequency Range 47 – 63Hz
Maximum Input Current 3.1Arms, 3.0Adc

All ratings apply for ambient temperatures up to 50°C (see Variations and Limitations below)
*Output power is reduced by 1%/V between 100V and 90Vac (225W max at 90Vac)
** Output power is reduced by 2%/V between 90V and 80Vac (180W max at 80Vac)
Output Parameters
The model variants listed below may be fan, forced air, conduction or convection cooled. The output parameters are shown in the table below.

CUS250M CH1 Outputs:

Model	Vout Range (V)	Max Iout (A)	Max Pout (W)
12	12 – 13.2	20.83	250
15	15-16.5	16.66	250
18	18-19.8	13.88	250
24	24 – 26.4	10.41	250
28	28-30.8	8.92	250
36	36-39.6	6.94	250
48	48-52.8	5.2	250

CUS250M Standby Output:

Model	Vout Fixed (V)	Max Iout (A)	Max Pout (W)
5	5	0.1	0.5

CUS250M Fan Output:

Vout Fixed (V)	Max Iout (A)
11.6	0.5

Variations and Limitations:
- Customer forced air cooling max ambient: 85°C (see note 1)
- Convection and conduction/cold plate cooling (U channel with cover, Option A) max ambient: 75°C (see note 1)
- Convection and conduction/cold plate cooling (U channel and open frame) max ambient: 80°C (see note 1)
- Fan cooling max ambient: 70°C (output power de-rated linearly by 2.5W/°C above 50°C)

Note 1: Maximum output power and current ratings are dependent on the ambient used in the end equipment.

Additional Information

• The product was submitted and evaluated for use at the maximum ambient temperature (Tma) permitted by the manufacturers specification of: 50°C maximum rated ambient (with appropriate deratings), 70°C maximum extended ambient for fan variants, 75°C maximum extended ambient for cover variants, 80°C maximum extended ambient for open frame and U Channel only variants.
• The total output power and current ratings are both de-rated to ensure power curves are met. Refer to the Instruction Manual included in Enclosure of this report.
• The tape, in transformers TX1 and TX300, is for mechanical support only and not safety critical.
see Enclosure "Additional application consideration" for more details regarding cooling and safe use.

The following tests were selected as representative of the test program applicable to model covered by this CBTR:

4.11 POWER INPUT
8.4.3 VOLTAGE OR CHARGE LIMITATION
8.7.4.6 TOUCH LEAKAGE CURRENT
8.8.3 DIELECTRIC VOLTAGE WITHSTAND
11 TEMPERATURE
13 ABNORMAL OPERATION TESTING
15.3.2 ENCLOSURE FORCE
These tests have been witnessed for models selected as representative of the standard covered by this report and the applicable test program.

Technical Considerations

- The product was investigated to the following standards:

  Main Standard(s):

  IEC 60601-1:2005+A1:2012

  From Country Differences:

  - Republic of Korea: KS C IEC 60601-1
  - USA: ANSI/AAMI ES60601-1:2005/(R)2012 and 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
  - Japan: National standard JIS T 0601-1:2017 (IEC 60601-1:2005 + A1:2012(MOD))
  - Israel: SI 60601 Part 1 (2018-06)

  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 (ISO 14971).
- 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:

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

- The following product-line tests are conducted for this product: Electric Strength, Earthing Continuity
- The end-product Electric Strength Test is to be based upon a maximum working voltage of: Primary-Secondary: 463 Vrms, 618 Vpk, Primary – Earthed Dead Metal: 408 Vrms, 562 Vpk
- The maximum investigated branch circuit rating is: 20A
- The investigated Pollution Degree is: 2
- The following end-product enclosures are required: Mechanical, Electrical, Fire
- The following magnetic devices (e.g. transformers or inductors) are provided with an OBJY2 insulation system with the indicated rating greater than Class A (105°C): TX1 (Class F), TX300 (Class B)
- The power supply was evaluated to be used at altitudes up to: 5000m for AC input; 3000m for DC input
- The power supply terminals and/or connectors are: Not investigated for field wiring
- The fan provided in this sub-assembly is not intended for operator access
- The power supply can be forced air (top fan or customer air versions), convection or conduction cooled. All variants that are not supplied with a fan are dependent on the end equipment application and

therefore testing must be carried out in the end equipment to ensure compliance with the stated component temperatures listed in the "Additional application considerations" section of this report.
• 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 voltages
• For option E (single fuse in the live line) the end equipment must be provided with a polarized plug
• Proper bonding to the end product main protective earthing termination is: required (except Class II applications)
• Where installed as a Class I power supply the protective bonding point must be verified in the end equipment
• Multilayer PWB's accepted under CBTR Ref. No E349607-A23 dated 2014-07-31 and Letter Report included in Enclosure '' Cemented Joint Letter Reports'' of this report.
• 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.

• 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 however the power supply needs to be fixed so that it is insulated from any unearthed accessible conductive part by reinforced insulation.
• A high breaking capacity Mains fuse, minimum 10 kA @ 125 V, shall be considered in the end-use product.
• Series operation is not permitted for this product.
• 12V output units utilizing the JST B4P-VH(LF)(SN) connector under Option L are restricted to 240W.

The following were not part of this submission and shall be assessed in the end application:
• The Risk management and Usability
• Clause 11.8 Interruption of the Power Supply
• Clause 7.2.2 Identification

Report Modifications

Date Modified *(Year-Month-Day)*	Modifications Made (include Report Reference Number)	Modified By
2021-11-12	Correction (C1) Test report E349607-D1017-1/A0/C0, issued 2021-10-26, has been modified to include the following corrections: 1- Removal of reference to B/BF applied parts from Insulation diagram Testing was not considered necessary; based on the results of the previous investigation. 2- Removal of schematics from enclosures	Ali Homaida
2022-08-30	Technical Amendment 1: Test report E349607-D1017-1/A0/C1, issued 2021-11-12 and CBTR E349607-D1017-1/A0/C1-CB issued on 2021-11-12 and CBTC DK-120167-C1-UL issued on 2021-11-12, has been modified to include the following: - Addition of the CUS250M Temperature testing at 90V under full load without de-rating. No other modifications introduced to the device.	Grzegorz Kowalski
2024-03-26	Technical Amendment 2: Test report E349607-D1017-1/A1/C1, issued 2022-08-30, has been modified to include the following: - model number has been updated with suffixes description and added new model numbers for DC input - Added factories TDK-LAMBDA MALAYSIA SDN BHD and TRIO-TRONICS (THAILAND) LTD; UL volume updated to	Maggie Chiu

	Vol.D6 - Added DC nominal supply voltage 133-318Vdc. - Minor consturction change including the change in no. of turns in the transformer. Minor spacing changes to PCB cut outs and plastic baseplate. - Added 15Vdc, 18Vdc, 28Vdc, 36Vdc, 48Vdc for CH1 output - Updated table 8.10 with the following: 1. adding alternate Fuses (F1, F2), type 477 series by littlefuse and UDE-A series by Conquer 2. adding alternate X Caps (C1), Y caps (C2, C3, C100, C102, C103) 3. adding alternate Auxiliary Controller IC (XU300) 4. adding transformer TX1 for 15V, 18V, 28V, 36V and 48Vdc output 5. adding daughter board insulator - Updated Enclosure with the changes listed above. Only limited testing was considered necessary based on the previously conducted testing and the review of product technical documentation.	