

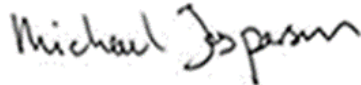



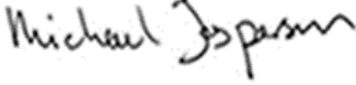



Test Report issued under the responsibility of:



<b>IEC 60601-1</b> <b>Medical electrical equipment</b> <b>Part 1: General requirements for basic safety and essential performance</b>	
<b>Report Number</b> .....	E349607-D1017-1/A0/C0-CB
<b>Date of issue</b> .....	2021-10-26
<b>Total number of pages</b> .....	256
<b>Name of Testing Laboratory preparing the Report</b> .....	UL International Demko A/S Borupvang 5A, DK-2750 Ballerup, Denmark
<b>Applicant's name</b> .....	TDK-Lambda UK Ltd
<b>Address</b> .....	Kingsley Avenue Ilfracombe, EX34 8ES UNITED KINGDOM
<b>Test specification:</b>	
<b>Standard</b> .....	IEC 60601-1:2005, AMD1:2012
<b>Test procedure</b> .....	CB Scheme
<b>Non-standard test method</b> .....	N/A
<b>TRF template used</b> .....	IECEE OD-2020-F1:2020, Ed.1.3
<b>Test Report Form No.</b> .....	IEC60601_1S
<b>Test Report Form Originator</b> .....	UL(US)
<b>Master TRF</b> .....	2020-12-17
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<b>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.</b>	
<b>General disclaimer:</b>	
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.	

<b>Test item description</b> .....:	Component switch mode power supply	
<b>Trade Mark(s)</b> .....	Trademark image(s): 	
<b>Manufacturer</b> .....	Same as Applicant	
<b>Model/Type reference</b> .....:	CUS250M series (See model differences for details of models and nomenclature)	
<b>Ratings</b> .....:	100 – 240Vac nominal, 3.1A max, 47-63Hz  (See model differences for details of ratings)	
<b>Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):</b>		
<input checked="" type="checkbox"/>	<b>CB Testing Laboratory:</b>	
<b>Testing location/ address</b> .....	UL International Demko A/S Borupvang 5A, DK-2750 Ballerup, Denmark	
<b>Tested by (name, function, signature)</b> .....	Ali Homaida, Project Engineer	
<b>Approved by (name, function, signature)</b> ..	Michael Jespersen, Reviewer	
<input type="checkbox"/>	<b>Testing procedure: CTF Stage 1:</b>	
<b>Testing location/ address</b> .....		
<b>Tested by (name, function, signature)</b> .....		
<b>Approved by (name, function, signature)</b> ..		
<input type="checkbox"/>	<b>Testing procedure: CTF Stage 2:</b>	
<b>Testing location/ address</b> .....		
<b>Tested by (name, function, signature)</b> .....		
<b>Witnessed by (name, function, signature)</b> ..		
<b>Approved by (name, function, signature)</b> ..		
<input checked="" type="checkbox"/>	<b>Testing procedure: CTF Stage 3:</b>	
<input type="checkbox"/>	<b>Testing procedure: CTF Stage 4:</b>	
<b>Testing location/ address</b> .....	TDK-Lambda UK Limited Kingsley Avenue Ilfracombe, EX34 8ES United Kingdom	

<b>Tested by (name, function, signature) .....</b> :	Matt Carter, Product Safety Engineer M.Gisbey, Trainee Product Safety Engineer	
<b>Witnessed by (name, function, signature) . :</b>	Maciej Gryczan, witness	See GPI for details
<b>Approved by (name, function, signature) .. :</b>	Michael Jespersen, Reviewer	
<b>Supervised by (name, function, signature) :</b>	Ali Homaida, Project Engineer	

**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:**

<b>Tests performed (name of test and test clause):</b>	<b>Testing location:</b>
<i>Refer to the Test List in Appendix B of this report if testing was performed as part of this evaluation.</i>	<i>Refer to the Test List in Appendix B of this report if testing was performed as part of this evaluation.</i>

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

List of countries addressed: Austria, Republic of Korea, USA, Canada, United Kingdom, Sweden, Japan, Israel

The product fulfils the requirements of IEC 60601-1:2005, AMD1:2012.

**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.

**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.*

<b>Test item particulars</b> .....	
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
<b>Possible test case verdicts:</b>	
- 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)
<b>Abbreviations used in the report:</b>	
- normal condition .....	N.C.
- means of Operator protection .....	MOOP
- single fault condition.....	S.F.C.
- means of Patient protection .....	MOPP
<b>Testing</b> .....	
<b>Date of receipt of test item</b> .....	2021-01-19 to 2021-08-12
<b>Date(s) of performance of tests</b> .....	2021-01-21 to 2021-09-02
<b>General remarks:</b>	
"(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 <input type="checkbox"/> comma / <input checked="" type="checkbox"/> point is used as the decimal separator.	
<b>Manufacturer's Declaration per sub-clause 4.2.5 of IEC60060-2:</b>	
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
<b>When differences exist; they shall be identified in the General product information section.</b>	
<b>Name and address of factory (ies)</b> .....	Same as Applicant
<p style="text-align: right;">Panyu Trio Microtronics Co Ltd SHIJI INDUSTRIAL ESTATE DONGYONG NANSHA GUANGZHOU GUANGDONG 511453CN China</p>	
<b>General product information and other remarks:</b>	

## 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 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

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.

## Model Differences

See Enclosure "Model Differences"

## Additional Information

- The product was submitted and evaluated for use at the maximum ambient temperature (T<sub>ma</sub>) 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 Handbook included in Enclosure "CUS250M Handbook" 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
- 8.8.3 Dielectric Voltage Withstand
- 11 Temperature
- 13 Abnormal Operation Testing

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:

- Austria: EN 60601-1:2006/A1:2013
- 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
- Sweden: SS-EN 60601-1:2006+A11:2011+A1:2013+AC1:2014+A12:2014
- Japan: National standard JIS T 0601-1:2017 (IEC 60601-1:2005 + A1:2012(MOD))
- Israel: SI 60601 Part 1 (2018-06)

Additional Standards:

EN 60601-1:2006/A1:2013/A12:2014, 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, Risk Management (ISO 14971).
- The following accessories were investigated for use with the product: N/A
- N/A

**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: 400 Vrms, 588 Vpk, Primary – Earthed Dead Metal: 375 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 OBJ2 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
- 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 2020-09-18 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.

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