
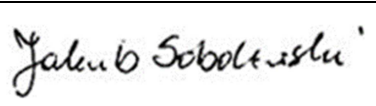




Test Report issued under the responsibility of:



IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	
Report Reference No.	E349607-D1006-1/A0/C0-CB
Date of issue	2017-11-16
Total number of pages	150
CB Testing Laboratory	UL International Germany GmbH Admiral Rosendahl Strasse 23 63263 Zeppelinheim/Neu-Isenburg Germany
Applicant's name	TDK-Lambda UK LTD Kingsley Avenue Ilfracombe, EX34 8ES UK
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
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General disclaimer:	
<p>The test results presented in this report relate only to the object tested.</p> <p>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.</p>	

Test item description:	Switch mode modular power supplies for installation into medical equipment	
Trade Mark:	TDK-Lambda	
Manufacturer:	Same as Applicant	
Model/Type reference:	CM4	
Ratings:	<p>CM4 input rating: 100-240 V ac nom, 7A rms max, 50-60Hz or 120-370 V dc, 7A max</p> <p>Output power is 600 W max</p> <p>Individual outputs rated according to modules fitted.</p> <p>Output modules ratings (rated output voltage marked on the device can be any values within the ranges specified below): S1 = 1.5 - 7.5Vdc, 25A, 125W S2 = 4.5 - 15Vdc, 15A, 150W S3 = 9 - 30Vdc, 7.5A, 150W S4 = 18 - 58Vdc, 3.75A, 150W</p> <p>All output modules current and power ratings are the maximum allowable.</p>	
Testing procedure and testing location:		
<input checked="" type="checkbox"/> CB Testing Laboratory:		
Testing location/ address:	UL International Germany GmbH Admiral Rosendahl Strasse 23 63263 Zeppelinheim/Neu-Isenburg Germany	
<input type="checkbox"/> Associated CB Testing Laboratory:		
Testing location/ address:		
Tested by (name, function, signature):	Hima Chetty (Handler)	
Approved by (name, function, signature):	Jakub Sobolewski (Project Reviewer)	
<input type="checkbox"/> Testing procedure: CTF Stage 1:		
Testing location/ address:		
Tested by (name, function, signature):		
Approved by (name, function, signature):		

<input type="checkbox"/>	Testing procedure: CTF Stage 2:	
Testing location/ address:		
Tested by (name, function, signature):		
Witnessed by (name, function, signature):		
Approved by (name, function, signature):		
<input type="checkbox"/>	Testing procedure: CTF Stage 3:	
<input type="checkbox"/>	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 B 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 to medical equipment
Mode of Operation:	Continuous
Supply Connection:	Connection to mains via host equipment
Accessories and detachable parts included:	None
Other Options Include:	
Testing	
Date of receipt of test item(s)	2016-04-20, 2016-06-21, 2016-10-21, 2016-08-23, 2016-10-17, 2017-09-27
Dates tests performed	2016-10-04 to 2016-11-30, 2017-10-03 to 2017-10-16
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:	
<p>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.</p> <p>"(See Attachment #)" refers to additional information appended to the report.</p> <p>"(See appended table)" refers to a table appended to the report.</p> <p>The tests results presented in this report relate only to the object tested.</p> <p>This report shall not be reproduced except in full without the written approval of the testing laboratory.</p> <p>List of test equipment must be kept on file and available for review.</p> <p>Additional test data and/or information provided in the attachments to this report.</p>	
Throughout this report a point is used as the decimal separator.	
Manufacturer's Declaration per sub-clause 4.2.5 of IEC 60601-1:2012	
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): Same as Applicant

Panyu Trio Microtronics Co. Ltd.
 SHIJI INDUSTRIAL ESTATE, DONGYONG,
 NANSHA, GUANGZHOU
 GUANGDONG 511453 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

CM4 is an AC/DC switch mode power supply series. The device uses fan-less, modular architecture based on selection of output modules. Unit can be configured with up to four output modules (in parallel / series combinations) that determine output ratings. The total output power is 600W (for de-ratings see additional information). Equipment is open-frame, uses metal baseplate and is intended for building-in to the host equipment.

The CM4 switch mode power supply consists of:

1. Input filter board and power conversion board (PRIMARY)
2. Planar transformer (PRI/SEC)
3. Output modules (SECONDARY)

Model Differences

N/A

Additional Information

CM4 Part No details:

CM4 xZ xY xY xY

Where x = Output voltage of the module fitted

Where Z = Module fitted in the slot

Where Y = Optional module (depending on total number of slots) or O for not fitted

The CM4 Series switch mode power supply can be configured in the following variations:

Sx = Single output S1, S2, S3, S4 as per table below

Zx = Modules S1, S2, S3 or S4 connected in parallel as per table below

Yx = Modules S1, S2, S3 or S4 connected in series as per table below

Hx = Modules S1, S2, S3 or S4 are combined (series connection of parallel connected modules) as per table below.

Where "x" can be any alphanumeric character

Module	#Slots	Output voltage range	Nominal Voltage	Output current	Rated Power
S1 125W	1	1.5Vdc - 7.5Vdc		5Vdc	25A
Z1 250W	2	1.5Vdc - 7.5Vdc		5Vdc	50A

ZA 375W	3	1.5Vdc - 7.5Vdc	5Vdc	75A
ZN 500W	4	1.5Vdc - 7.5Vdc	5Vdc	100A
Y1 250W	2	3Vdc - 15Vdc	10Vdc	25A
HA 500W	4	3Vdc - 15Vdc	10Vdc	50A
S2 150W	1	4.5Vdc - 15Vdc	12Vdc	15A
Z2 300W	2	4.5Vdc - 15Vdc	12Vdc	30A
YA 375W	3	4.5Vdc - 22.5Vdc	15Vdc	25A
ZB 450W	3	4.5Vdc - 15Vdc	12Vdc	45A
ZP 600W	4	4.5Vdc - 15Vdc	12Vdc	60A
YN 500W	4	6Vdc - 30Vdc	20Vdc	25A
S3 150W	1	9Vdc - 30Vdc	24Vdc	7.5A
Y2 300W	2	9Vdc - 30Vdc	24Vdc	15A
ZC 450W	3	9Vdc - 30Vdc	24Vdc	22.5A
HB 600W	4	9Vdc - 30Vdc	24Vdc	30A
ZQ 600W	4	9Vdc - 30Vdc	24Vdc	30A
YB 450W	3	13.5Vdc - 45Vdc	36Vdc	15A
S4 150W	1	18Vdc - 58Vdc	48Vdc	3.75A
Y3 300W	2	18Vdc - 60Vdc	48Vdc	7.5A
ZD 450W	3	18Vdc - 58Vdc	48Vdc	11.25A
ZR 600W	4	18Vdc - 58Vdc	48Vdc	15A
YP 600W	4	18Vdc - 60Vdc	48Vdc	15A
YC 450W	3	27Vdc - 90Vdc	72Vdc	7.5A
Y4 300W	2	36Vdc - 116Vdc	96Vdc	3.75A
YQ 600W	4	36Vdc - 120Vdc	96Vdc	7.5A
YD 450W	3	54Vdc - 174Vdc	144Vdc	3.75A
YR 600W	4	72Vdc - 232Vdc	192Vdc	3.75A

Input Parameters:

Nominal input voltage 100 – 240 Vac (or 120 – 370 V dc)

Input voltage range 85 – 264 Vac (or 120 – 370 V dc)

Input frequency range 50 – 60 Hz

Maximum input current 7 A rms (fuse 8 A)

The total output power is 600 W from output modules plus 5 W bias power from J5-Global connector (5 V dc, 1 A).

The following power deratings are applicable:

a. Line voltages <120 V ac:

600 W @ 120 V ac to 425 W @ 85 V ac (linear, applies to input and output power)

b. baseplate temperatures > 85°C:

600 W @ 85°C TO 300 W @ 105°C (linear, applies to output power and bias power)

Baseplate temperature shall be measured on the TS1 reference point defined in the Diagram-01 (see Enclosures).

c. ambient temperatures > 50°C:

600 W @ 50°C to 300 W @ 70°C (linear, applies to input power)

Line deratings and temperature deratings are cumulative.

Technical Considerations

- The product was investigated to the following standards:

Main Standard(s):

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/ A11:20011/ A1:2013/ 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 secondary output circuits are at hazardous energy levels: output modules S2, S3.

The following secondary output circuits are non-hazardous energy levels: S1, S4, J5-Global bias, J5-Output bias.

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: 20 A

The investigated pollution degree is: II

Proper bonding to the end product main protective earthing termination is: required

The following end-product enclosures are required: Mechanical, Fire, Electrical

The product was tested for use at the maximum ambient temperature (TMA) 70° C (with deratings above 50°C – see additional information for details)

An investigation of the protective bonding terminals has been conducted

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.

The product was evaluated for use at the maximum altitude of operation: 3000 m

Component power supply, risk management requirements of the standard were not addressed, to be considered as part of end-product. refer to OD 2055:2015 for further details.

The marking requirements of Clauses 7.2, 7.3 & 7.5 must be considered in the end product application.

Report Modifications

Date Modified (Year-Month-Day)	Modifications Made (include Report Reference Number)	Modified By

IEC 60601-1

Clause	Requirement + Test	Result - Remark	Verdict
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Insulation Diagram - (01) INSULATION DIAGRAM

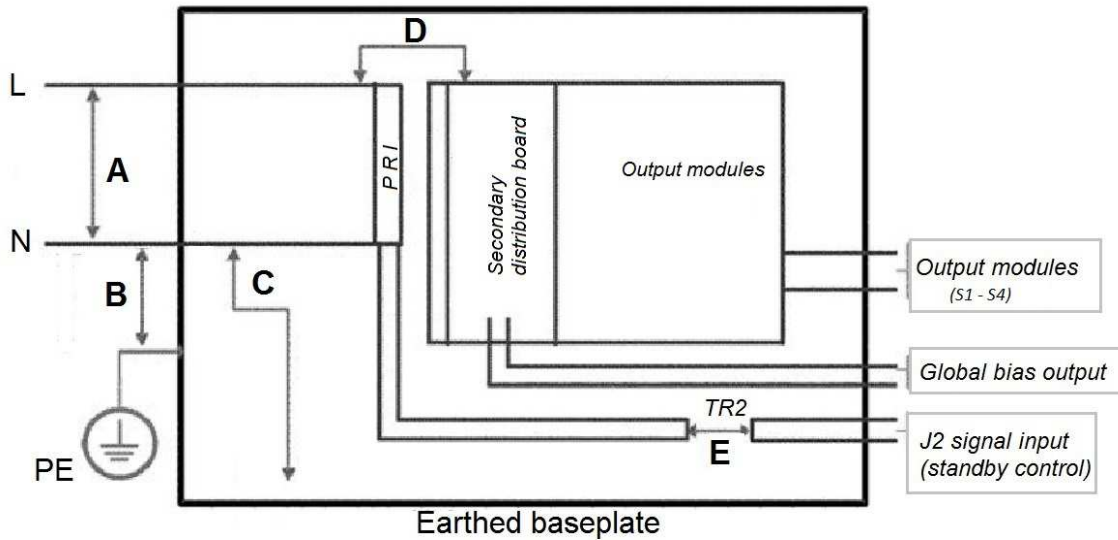


TABLE: INSULATION DIAGRAM									Pass
Pollution Degree:		2							-
Overvoltage category:		II							-
Altitude:		3000 (m)							-
Additional details on parts considered as applied parts:		[X] None [] Areas: ____ (See Clause 4.6 for details)							-
Area	Number and type of Means of Protection: MOOP, MOPP	CTI	Working Voltage V_{rms}	Working Voltage V_{pk}	Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
A	MOOP (1)	IIIb	240	340	2.4	2.3	3	3	L to N (parts of opposite polarity), on PWB and between fuse clips.
B	MOPP (1)	IIIb	240	340	4	2.5	7	7	L/N to PE (on input terminal)
C	MOPP (1)	IIIb	296	412	4.7	3.5	10	10	PRIMARY (HV_bus) to PE (earthed baseplate)
D	MOPP (2)	IIIb	221	336	7.6	5	9	10	PRIMARY to SECONDARY in planar transformer

IEC 60601-1									
Clause	Requirement + Test					Result - Remark			Verdict
E	MOPP (2)	IIIb	5.6	6	3.4	1.6	9	11	PRIMARY to SECONDARY in T2 signal transformer
<p>Supplementary Information:</p> <p>INSULATION DIAGRAM CONVENTIONS and GUIDANCE:</p> <p>A measured value must be provided in the value columns for the device under evaluation. The symbol > (greater than sign) must not be used. Switch-mode power supplies must be re-evaluated in the device under evaluation therefore N/A must not be used with a generic statement that the component is certified. Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:</p> <ul style="list-style-type: none"> - All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances. - Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional - Applied parts are extended beyond the equipment enclosure and terminated with an arrow. - Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow. 									