
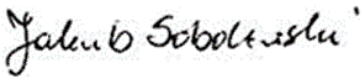




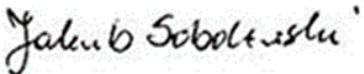



Test Report issued under the responsibility of:



IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	
Report Number	E349607-D1018-1/A0/C0-ULCB
Date of issue	2022-07-08
Total number of pages	240
Name of Testing Laboratory preparing the Report	UL VS Limited Unit 1 – 3 Horizon, Wade Road Kingsland Business Park Basingstoke RG24 8AH United Kingdom
Applicant's name	TDK-LAMBDA UK LTD
Address	KINGSLEY AVE 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
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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): 	
Manufacturer	Same as Applicant	
Model/Type reference:	MU Series, limited to: zMU4FSDdef-ghi, zMU4FSEdef-ghi zMU4FSFdef-ghi, zMU4FSGdef-ghi Where z, d, e, f, -ghi are alphanumeric characters specified in model differences section.	
Ratings:	zMU4FSDdef-ghi, zMU4FSEdef-ghi Input: 100 - 240Vac, 8A rms, 47 - 63Hz, Output:600W 200 - 240Vac, 6A rms, 47 - 63Hz, Output:800W zMU4FSFdef-ghi, zMU4FSGdef-ghi input: 144 - 318Vdc, 6Adc, Output:600W 278 - 318Vdc, 4.1Adc, Output:800W	
Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):		
<input checked="" type="checkbox"/>	CB Testing Laboratory:	
Testing location/ address	UL VS Limited Unit 1 – 3 Horizon, Wade Road Kingsland Business Park Basingstoke RG24 8AH United Kingdom	
Tested by (name, function, signature)	Hubert Koszewski, Project Engineer	
Approved by (name, function, signature) .. :	Jakub Sobolewski, 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 checked="" type="checkbox"/>	Testing procedure: CTF Stage 3:	
<input type="checkbox"/>	Testing procedure: CTF Stage 4:	
Testing location/ address		TDK-Lambda UK Limited Kingsley Avenue Ilfracombe, EX34 8ES United Kingdom
Tested by (name, function, signature)		Nick Marsh, Product Safety Engineer 
Witnessed by (name, function, signature) . .		Hubert Koszewski, Project Engineer 
Approved by (name, function, signature) ..		Jakub Sobolewski, Reviewer 
Supervised by (name, function, signature) :		Hubert Koszewski, 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:**Tests performed (name of test and test clause):**

Refer to the Test List in Appendix D of this report if testing was performed as part of this evaluation.

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):

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

The product fulfils the requirements of.

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.

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.
- means of Operator protection	MOOP
- single fault condition.....	S.F.C.
- means of Patient protection	MOPP
Testing	
Date of receipt of test item	2020-11-20 to 2022-02-11
Date(s) of performance of tests	2020-11-20 to 2022-02-11
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 <input type="checkbox"/> comma / <input checked="" type="checkbox"/> point is used as the decimal separator.	
Manufacturer's Declaration per sub-clause 4.2.5 of IEC60060-2:	
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 and other remarks:**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 MU series of switch mode power supply consists of:

Main board

1. Input filter, consisting of the input fuse(s), X and Y capacitors, common mode chokes up to the bridge.
2. PFC (boost circuit), consisting of the boost choke and associated switching FETs/circuitry.
3. Fan output
4. Forward converter switching circuitry

Module boards

5. Main transformer.
6. Secondary circuits, consisting of Module output and signals.

Primary options

7. Consisting of the transformer and switching IC/circuitry supplying the Primary Option output.
8. Secondary circuits, consisting of Primary Option output and signals.

Refer to Enclosure "Model Differences" for details of nomenclature.

Model Differences

This report covers the MU series of switch mode power supplies. The MU series consists of a 4 slot model (MU4), with each slot capable of fitting a single module. The MU4 is available as 600W or 800W depending on the input voltage. Global option and PMBus Standby Options may be fitted.

MU modules nomenclature (Description):

zMUabcdef-ghi for modular configurations

Where z = Blank for standard product
 NS # followed by / or - (where # may be any number of characters indicating non-safety related model differences).
 SP followed by / or - (SP represents a sales code)

s = (Number of slots)
 4 for MU4 models

a = (Cooling)
 F for variable speed, forward air

b = (Input connection)
 S for screw

c = (Input fusing)
 D for dual AC fuse
 E for single AC fuse in the live line
 F for dual AC/DC fuses
 G for single AC/DC fuse in the +ve input line

d = (Leakage current)
 L for 300uA

R for 150uA

e = (Primary option)
Blank for none fitted
E5H for global enable with 5V standby
T5H for global inhibit with 5V standby
Q5xxxxx for 5V PMbus (where x may be any
number or letter)

f = -CO for coating
-COx for alternative coating (where x maybe any number)
Blank for no coating

May be followed by non-safety related changes/options:

-ghi

Where ghi = Any 3 characters which may define non-safety related parameters/features, e.g
reduced primary current limit, reduced OVP and coatings etc...
Blank for standard unit

Output modules nomenclature:

Single output modules

vMcd

Where v = Output voltage, may be 5, 12, 24 or 48
M = SB (Module name)
c = S for screw (Output terminal)
d = See letter from Module Signal Option Table

Blanking plates

B/S

Where B/S = Blanking plate

Parallel output modules

vZxcd

Where v = Output voltage, may be 5, 12, 24 or 48
Z = Paralleled modules using SB modules
x = Number of slots. Refer to Parallel and Series Combination Tables
c = S for screw (Output terminal)
d = See letter from Module Signal Option Table

Series output modules

vYxcd

Where v = Output voltage, may be 5, 12, 24 or 48
Y = Series modules using SB modules

x	=	Number of slots. Refer to Parallel and Series Combination Tables
c	=	S for screw (Output terminal)
d	=	See letter from Module Signal Option Table

Series connected Paralleled modules

vHxcd

Where	v	=	Output voltage, may be 5, 12, 24 or 48
	H	=	Series connected parallel SB
	x	=	Number of slots. Refer to Parallel and Series Combination Tables
	c	=	S for screw (Output terminal)
	d	=	See letter from Module Signal Option Table

Units may be marked with a Product Code: KMUxy where x is the number of available slots and y may be any number of characters and K is a prefix that is used for a product code. This is an internal code only and is not part of the model nomenclature.

Refer to Tables in the Enclosures for the Module Signal Option Table, Parallel and Series Combination Tables, Input Parameters, Output Parameters Table, Series Modules Table and Cooling Options MU4 Table.

Additional information

- 600W and 800W AC input PSU Models are identical in hardware, the only difference is the input rating, so that the end application use will determine input rating to be used depending on the output required
- 600W and 800W DC input PSU Models are identical in hardware, the only difference is input rating, so that the end application use will determine input rating to be used depending on the output required

Additional Information

Multilayer PWB's accepted under CBTR Ref. No: E349607-A23 dated 2014-07-31 and letter Report, see Enclosure "Multi-layer_PWB_Letter_Reports" of this report.

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

- The following additional investigations were conducted: N/A
- The product was not investigated to the following standards or clauses: Scope of Power Supply evaluation defers the following clauses to be determined as part of the end product investigation:
 - Clause 7.5 (Safety Signs),
 - Clause 7.9 (Accompanying Documents),
 - Clause 9 (ME Hazard), except 9.1 and 9.3 are evaluated,
 - Clause 10 (Radiation),
 - Clause 14 (PEMS),
 - Clause 16 (ME Systems)
 - Risk Management was excluded from this investigation.
 - 12.2 USABILITY of ME EQUIPMENT (IEC 60601-1-6)
- 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 end-product Electric Strength Test is to be based upon a maximum working voltage of: Primary to Secondary circuits: 468Vrms, 541Vpk, (Primary-Earthed Dead Metal: 406Vrms, 558Vpk, Secondary Outputs-Earthed Dead Metal: 240Vrms, 340Vpk.
- The following secondary output circuits are below 60Vdc, 42.4Vpk: All except 48V SB module and specific series modules. Refer to Model Differences for series modules which may not be below 60Vdc, 42.4Vpk.
- The following secondary output circuits are at hazardous energy levels: All modules except those listed as non-hazardous
- The following secondary output circuits are non-hazardous energy levels: 5V SB module, 5V primary options.
- Proper bonding to the end product main protective earthing termination is required
- An investigation of the protective bonding terminals has been conducted
- The following end-product enclosures are required: Mechanical, Fire, Electrical
- The following magnetic devices (e.g. transformers or inductor) are provided with an OBJ3 insulation system with the indicated rating greater than Class A (105°C): TX1, SB modules and Global options Class F (155°C). See Critical Components Table for details of insulation systems used.
- Fans: The fan provided in this sub-assembly is not intended for operator access
- The product was evaluated for use at the maximum altitude of operation: 4000 m
- 1 x MOPP isolation is possible between modules separated by a blanking slot. Non-standard models only.
- The Maximum ambient temperature is 45°C for 600W output rated PSUs
- The Maximum ambient temperature is 50°C for 800W output rated PSUs
- An elevated Tma (for example 50°C) can be considered and evaluated in the end use application allowing for specific load and input conditions.
- For all models, output power derated by 2.5% per °C above 50°C, up to 70°C max.
- For 600W output rated models, 50°C is achievable with input voltages above 111Vac input or

160Vdc input. Ambient is de-rated from 50°C down to 45°C, linearly, with input voltages from 111Vac down to 100Vac, or 160Vdc down to 144Vdc.

Report Modifications

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