









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-D1012-1/A0/C0-CB
Date of issue	2019-10-06
Total number of pages.....	164
CB Testing Laboratory.....	UL International Demko A/S Borupvang 5A, DK-2750 Ballerup, Denmark
Address	
Applicant's name.....	TDK-LAMBDA UK LTD
Address	KINGSLEY AVE, 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
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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:	Medical Switch Mode Power Supply	
Trade Mark:	Trademark image(s):	
		
Manufacturer	Same as Applicant	
Model/Type reference:	EFE400M or EFE-400M series (see Model Differences for details of models and nomenclature)	
Ratings:	94.5-240Vac nom, 45-63Hz, 6.1A rms max. or 100-240Vac nom, 45-63Hz, 6.1A rms max. (See Model Differences for details of ratings)	
Testing procedure and testing location:		
<input checked="" type="checkbox"/> CB Testing Laboratory:		
Testing location/ address	UL International Demko A/S Borupvang 5A, DK-2750 Ballerup, Denmark	
<input type="checkbox"/> Associated CB Testing Laboratory:		
Testing location/ address		
Tested by (name, function, signature)	Hedieh Naderi, Handler	
Approved by (name, function, signature)	Michael Jespersen, Reviewer	
[] 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	TDK-Lambda UK Limited Kingsley Avenue, Ilfracombe Devon, EX34 8ES United Kingdom	
Tested by (name, function, signature)	Nick Marsh, Tester	
Witnessed by (name, function, signature) ...:	N/A	
Approved by (name, function, signature)	Michael Jespersen, Approver	
Supervised by (name, function, signature) ..:	Hedieh Naderi, 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.

Summary of compliance with National Differences

List of countries addressed: USA, Canada

[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:	For building in
Device type (component/sub-assembly/ equipment/ system):	Component
Intended use (Including type of patient, application location):	To supply regulated power
Mode of Operation:	Continuous
Supply Connection:	For building into host equipment
Accessories and detachable parts included:	None
Other Options Include:	None
Testing	
Date of receipt of test item(s)	2014-11-21 and 2019-06-03
Dates tests performed	2014-12-01 to 2015-01-15 and 2019-06-11
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 (collateral standards only)
- test object does not meet the requirement.....	Fail (F)
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
General remarks:	
<p>"(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.</p> <p>Throughout this report a point is used as the decimal separator.</p>	
Manufacturer's Declaration per sub-clause 4.2.5 of IEC60601-1:2012	
<p>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</p>	
<p>When differences exist; they shall be identified in the General product information section.</p>	

Name and address of factory (ies)..... : Same as Applicant

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

Medical Switch Mode Power Supply (see Model Differences for details of models and nomenclature)

- The product was not investigated to the following standards or clauses:: Electromagnetic Compatibility (IEC 60601-1-2), Clause 14, Programmable Electronic Systems, Biocompatibility (ISO 10993-1)
- The degree of protection against harmful ingress of water is:: Ordinary
- The mode of operation is:: Continuous
- The product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide:: No
- Risk Management has not been applied to these products.
- Options include a variable speed (temperature controlled) fan.
- Multilayer PWB's accepted under CBTR Ref. No. E349607-A23 dated 2014-07-31 and letter report Enclosure 8-05 of this report.

1. 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.

2. Risk Controls/ Engineering Considerations for component power supply:

For use only in or with complete equipment where the acceptability of the combination is determined by the CB Testing Laboratory, when installed in an end-product, consideration must be given to the following:
For Power Supplies with No RM: End product Risk Management Process to include consideration of requirements specific to the Power Supply.

Model Differences

EFE400M or EFE-400M models as described below:

Units may be marked with a Product Code: U6x or Y6x where x may be any number of characters.

Unit Configuration Code (Description :) may be prefixed by NS # followed by / or - (where # may be any number of characters indicating non- safety related model differences).

Unit Configuration Code (Description :) may be prefixed by SP followed by / or – (SP represents a sales code)

Unit Configuration Code: EFE400Mxy-a-b-cdef-gh-i-j-klm where:

x = Nothing or J for Japanese models (may have non-safety differences).

y = Blank for Y2 capacitors from output to earth P for Y1 capacitors from output to earth
D for Class II (with Y1 capacitors)

a = Channel 1 output Voltage (see Ch1 in the table below, adjustment range column).

b = Standby voltage: see standby voltage in table below.

c = BC for cover and U chassis without fan grill, with fan fitted (temperature controlled). (Y60001x model only)

HN for Open frame, no fan, with 12V / 1A fan supply.

HU for U chassis (not EFE400MxD models), no fan, with 12V / 1A fan supply.

HC for Cover + chassis (not EFE400MxD models), no fan, with 12V / 1A fan supply.

EC for Cover + chassis (not EFE400MxD models), end fan (temp controlled).

NN for Open frame, no fan, no fan supply.

NU for U chassis (not EFE400MxD models), no fan, no fan supply.

NC for Cover + chassis (not EFE400MxD models), no fan, no fan supply.

HP for perforated cover, no fan, with 12V / 1A fan supply.

NP for perforated cover, no fan, no fan supply.

d = M for Molex KK type 41791 input connector or equivalent.

S for Molex Sabre type 43160 input connector or equivalent.

e = D for AC input with dual fusing.

F for AC/DC input with dual fusing.

E for single fuse input in the Live line.

G for single fuse input in the + line

f = L for low Leakage.

R for reduced Leakage.

T for tiny Leakage.

Z for EFE400MxD models (Class II).

where L < 300uA leakage, R < 150uA leakage and T < 75uA leakage.

g = Y for Oring FET included.

N for no Oring FET.

h = T for inhibit.

E for enable.

N for no remote signals

i = V for vertical output connector or nothing for horizontal output connector.

j = Nothing for standard channel 1 output voltage, xD or xPD where D is for units with programmed negative load regulation, PD is for units with programmed positive load regulation, x is the voltage of the regulation in 100mVolts and is within the Output Adjustment range (example, 7D = 0.7V of negative load regulation, 18PD = 1.8V of positive load regulation).

klm = Three numbers from 0 to 9 which denotes various output voltage/current settings within the specified ranges of each output for a particular unit or blank for standard output settings. (may define non-safety related parameters/feature, e.g. reduced primary current limit, reduced OVP)

Input Parameters

Standard	60601-1
Nominal input voltage	100 - 240 Vac