Test Report issued under the responsibility of:

TEST REPORT
IEC 60601-1
Medical Electrical Equipment
Part 1:General requirements for safety

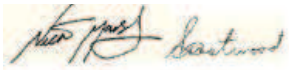
Report Reference No ..... :	E349607-A8-CB-2
Date of issue ..... :	2015-10-09
Total number of pages ..... :	124
CB Testing Laboratory ..... :	UL International Germany GmbH
Address ..... :	Admiral-Rosendahl-Strasse 23, 63263 Neu-Isenburg (Zeppelinheim), Germany
Applicant's name ..... :	TDK-LAMBDA UK LTD
Address ..... :	KINGSLEY AVE ILFRACOMBE DEVON EX34 8ES UNITED KINGDOM
Test specification:	
Standard ..... :	IEC 60601-1:1988 + A1:1991 + A2:1995
Test procedure ..... :	CB Scheme
Non-standard test method ..... :	N/A
Test Report Form No. ..... :	IEC60601_1c/97-04
Test Report Form originator ..... :	UL LLC
Master TRF ..... :	dated 97-04

This report is not valid as a CB Test Report unless signed by an approved CB 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 CB Testing Laboratory. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.

Test item description	:	Medical Switch Mode Power Supply
Trade Mark	:	TDK-Lambda
Manufacturer	:	TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE DEVON EX34 8ES UNITED KINGDOM
Model/Type reference	:	EFE300M Series (see model differences for details of models and nomenclature)
Ratings	:	100-240Vac nom, 45-63Hz, 4.9A rms max. (see model differences for details of models and ratings)

Testing procedure and testing location:			
[ ]	**CB Testing Laboratory**		
	Testing location / address..... :		
[ ]	**Associated CB Test Laboratory**		
	Testing location / address..... :		
	Tested by (name + signature) ..... :		
	Approved by (name + signature) ... :		
[ ]	**Testing Procedure: TMP/CTF Stage 1**		
	Tested by (name + signature) ..... :		
	Approved by (+ signature) ..... :		
	Testing location / address..... :		
[ ]	**Testing Procedure: WMT/CTF Stage 2**		
	Tested by (name + signature) ..... :		
	Witnessed by (+ signature)..... :		
	Approved by (+ signature) ..... :		
	Testing location / address..... :		
[x]	**Testing Procedure: SMT/CTF Stage 3 or 4**		
	Tested by (name + signature) ..... :	N. S. Marsh, S. Hirstwood	
	Approved by (+ signature) ..... :	K. P. tizzard	
	Supervised by (+ signature) ..... :	Dennis Butcher	
	Testing location / address..... :	TDK-Lambda UK. Ltd, Kingsley Avenue, Ilfracombe, Devon, EX34 8ES	
[ ]	**Testing Procedure: RMT**		
	Tested by (name + signature) ..... :		
	Approved by (+ signature) ..... :		
	Supervised by (+ signature) ..... :		
	Testing location / address..... :		

List of Attachments
National Differences (16 pages)
Enclosures (174 pages)
Summary of Testing:
All Applicable tests according to the referenced standard(s) have been carried out

Summary of Compliance with National Differences:

Countries outside the CB Scheme membership may also accept this report.

List of countries addressed: AT, AU, BE, BR, CA, CH, CZ, DE, DK, FI, FR, GB, GR, HU, IL, IN, IT, JP, KR, NL, NO, PL, RU, SE, SI, SK, UA, US

The product fulfills the requirements of: EN 60601-1: 1990 + A1:1993 + A2:1995 UL 60601-1, 1st Edition, 2006-04-26 (includes National Differences for USA) CAN/CSA-C22.2 No. 601.1-M90 (R2005) (includes National Differences for Canada)

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.

Test item particulars :				
Classification of installation and use		For building into host equipment		
Supply connection		Connection to mains via host equipment		
Accessories and detachable parts included in the evaluation		None		
Options included		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 does not meet the requirement		F(Fail)		
Abbreviations used in the report:				
- normal condition	N.C.	- single fault condition		S.F.C.
- operational insulation	OP	- basic insulation		BI
- basic insulation between parts of opposite polarity:	BOP	- supplementary insulation		SI
- double insulation	DI	- reinforced insulation		RI
Testing:				
Date(s) of receipt of test item		2014-12-03 to 2015-01-05		
Date(s) of Performance of tests		2014-12-09 to 2015-01-07		
General remarks: List of test equipment must be kept on file and be available for review. "(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 point is used as the decimal separator.				
Manufacturer's Declaration per Sub Clause 4.2.5 of IECEE 02:				Yes
The application for obtaining a CB Test Certificate includes more than one factory 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 ..... When differences exist, they shall be identified in the General Product Information section.				
Name and address of Factory(ies):	TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE DEVON EX34 8ES UNITED KINGDOM PANYU TRIO MICROTRONIC CO LTD SHIJI INDUSTRIAL ESTATE DONGYONG NANSHA GUANGZHOU GUANGDONG CHINA			

TDK-LAMBDA CORP
2704-1 SETTAYA-MACHI
NAGAOKA-SHI
NIIGATA-KEN 940-1195 JAPAN

GENERAL PRODUCT INFORMATION:

Report Summary

All applicable tests according to the referenced standard(s) have been carried out.

Product Description

The EFE300M Series are switched mode power supplies for building into host equipment

Model Differences

Nominal Input Voltage Range	100 - 240V AC
Maximum Input Voltage Range	90** - 264V AC
Input Frequency	45-63Hz
Maximum Input Current	4.9A rms

** Channel 1 output is linearly derated from 90Vac to 85Vac, 4W per volt to 280W.

All ratings apply for ambient temperatures up to 50°C. From 50 to 70°C the output power is derated at 2.5% per deg C.

EFE300M or EFE-300M models as described below:
(may be prefixed by NS - # / where # may be any number of characters indicating non safety related model differences)
Products may additionally be marked with U5x or Y5x where x can be any number of characters indicating non-safety related model differences.

Unit Configuration Code: EFE300Mxy-a-b-cdef-ghijk
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.
a= Channel 1 output Voltage: see Ch1 in the outputs table below, adjustment range column.
b= Standby voltage: see standby voltage table below or 0 for omitted
c= HN for Open frame, no fan, with 12V / 1A fan supply. HU for U chassis, no fan, with 12V / 1A fan supply. HC for Cover + chassis, no fan, with 12V / 1A fan supply. EC for Cover + chassis, end fan (temp controlled). NN for Open frame, no fan, no fan supply. NU for U chassis, no fan, no fan supply. NC for Cover + chassis, no fan, no fan supply. CN for Open frame, no fan, with 12V / 0.25A fan supply. CU for U chassis, no fan, with 12V / 0.25A fan supply. CC for Cover + chassis, no fan, with 12V / 0.25A fan supply.
d= M for molex input connector or equivalent, J for JST connector or equivalent.
e= D for dual fused input or L for single fuse in the live line
f= S for standard Leakage, L for low Leakage, R for reduced Leakage, T for tiny Leakage. *
g= Y for Oring FET included or N for nothing.
h= E for enable, T for inhibit, N for no inhibit, no enable.
i= Nothing for horizontal output connector, -V for vertical output connector, -S for screw terminal

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, 24PD = 2.4V of positive load regulation).
k= Nothing or -x where x is 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)

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

Output parameters:

O/P Channel	Vout nom (V).	Range (V)	Max O/P (A)	Max O/P (W)
CH1	12	11.4 - 13.2*	25	300 (400**)
	24	22.8 - 26.4*	12.5	300 (400**)
	28	27 - 32*	10.72	300 (400**)
	40	36 - 42*	7.5	300 (350***)
	48	47 - 50*	6.25	300 (350***)
	50	50.1 - 54*	6.0	300 (350***)
Standby	5	Fixed	2	10
	12	Fixed	1	12
	13.5	12-13.5*	1	13.5
Fan output	12	Fixed	0.25	3
	12	Fixed	1	12

* Can be adjusted from nominal at the factory only.
** Peak power of 400W for 10 seconds maximum, maximum rms power of 300W:
*** Peak power of 350W for 10 seconds maximum, in any 1 minute cycle, maximum rms power of 300W:

where T1 = peakpower time on
and T2 = reduced power time on

Maximum continuous power output 300W (excluding fan output)

Output Limitations

All standard outputs are SELV up to and including 48V nominal. Voltages above 48V nominal are non SELV and must not be accessible to an end operator..
All outputs have basic spacings to earth, and due consideration must be given to this in the end product design.

Non Standard models.

Model: Y5J008# (where # can be any letter) or EFE300MJ-12.1-5-008 or EFE300MJ-12.1-5-008-SGP
Maximum outputs: 12.1V, 21.49A, plus 5V, 2A standby.
Maximum ambient: As standard model.
Orientations: As standard model.
Comments:. Fan speed is controlled at 6600rpm up to and between 45 to 50°C ambient after which the fan speed increases to typically 10,000rpm (10V). Can be fitted with or without fan guard.

Model: Y5J006# (where # can be any letter) or EFE300MJ-12-5-006.

Maximum outputs: 11.4V to 13.2V*, 25A, (300W max) plus 5V, 2A standby.
Maximum ambient: As standard model.
Orientations: As standard model.
Comments: Longer version than standard model to accommodate additional reservoir capacitor for a greater hold up time.

Model: Y5J015# (where # can be any letter) or EFE300MJ-12.1-5-009 or EFE300MJ-12.1-5-009-SGP
Maximum outputs: 12.1V, 24.79A plus 5V, 2A standby.
Main output may also be 11.4 to 13.2V at 25A max. limited to 300W max.
Maximum ambient: As standard model.
Orientations: As standard model.
Comments: Model is the same as Y5J008# but is a NN.

Additional Information

This report is a reissue of CBTR Ref. No:E349607-A8-CB-1 dated2011-11-29 including amendments and corrections with CB test certificate Ref. No: DK-5208-A3-UL dated 2014-06-30.
Add alternate components in the list of the Critical Components List.
Change of factory name from "TRIO ENGINEERING CO LTD" to "PANYU TRIO MICROTRONIC CO LTD"
Based on the previously conducted testing and review of the product technical documentation including photos, schematics, wiring diagrams and similar it has been determined that the product continues to comply with the standard.

Only the tests listed below were deemed necessary.
Abnormal (Clause 52). Dielectric Voltage Withstand(Clause 20.4) F2, alternative fuse test, non critical part, (not mains input). Temperature (Clause 42). Alternative fan test.

Technical Considerations

- The product was investigated to the following additional standards: EN 60601-1: 1990 + A1:1993 + A2:1995, UL 60601-1, 1st Edition, 2006-04-26 (includes National Differences for USA), CAN/CSA-C22.2 No. 601.1-M90 (R2005) (includes National Differences for Canada)
- The product was not investigated to the following standards or clauses: Clause 52.1, Programmable Electronic Systems (IEC 601-1-4), Clause 48, Biocompatibility (ISO 10993-1), Clause 36, Electromagnetic Compatibility (IEC 601-1-2)
- The product is Classified only to the following hazards: Fire,, Shock
- The degree of protection against harmful ingress of water is: Ordinary (IPX0)
- The mode of operation is: Continuous
- The product was submitted and tested for use at the maximum ambient temperature (Tma) permitted by the manufacturer¿s specification of: 50°C (full load); 70°C (output power decreasing linearly by 2.5%/°C above 50°C) --
- The applicant has declared the outputs as SELV for voltages up to and including 48V nominal. Testing has therefore been applied to ensure compliance with the limits specified in clause 2.4.3 --
- Multi-layer PWB's accepted under CBTR Ref. No. E349607-A23 dated 2014-07-31 and letter report, Enclosure 8-06 of this report. --

Engineering Conditions of Acceptability

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

- Insulation (Separation) between primary - secondary output circuits: Double/Reinforced. --
- Insulation (Separation) between primary - earth: BASIC --
- Insulation (Separation) between secondary circuits - earth: BASIC (at mains). --
- Branch circuit protection required: 16A (20A For North America and Canada) --
- The following outputs are considered SELV:All standard outputs are SELV up to and including 48V nominal. Voltages above 48V nominal are non SELV and must not be accessible to an end operator.. , All outputs have basic spacings to earth, and due consideration must be given to this in the end product design, except for Y50029# which has functional spacings to earth. , --
- Some PWB mounted components are rated at the minimum coating rating of 125°C. --
- The client has declared that due to component tolerances, the voltage of the 50V output may exceed the limits of SELV as defined in 2.4.3 (greater than 60Vdc). In the end use equipment, either a level of Supplementary protection must be provided or the end use evaluation should establish an acceptable level of risk where the 50V output is used. --
- Consideration should be given to repeating the Earth LeakageTests in the end use equipment. --