




Test Report issued under the responsibility of:





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|---|---|
| <b>TEST REPORT</b><br><b>IEC 60601-1</b><br><b>Part 1: General requirements for basic safety and essential performance</b>  |   |
| Report Number .....   | E349607-D6  |
| Date of issue .....   | 2015-05-12  |
| Total number of pages.....  | 175   |
| Name of Testing Laboratory preparing the Report.....  | UL International Demko A/S<br>Borupvang 5A<br>2750 Ballerup, Denmark  |
| Applicant's name.....   | TDK-LAMBDA UK LTD   |
| Address .....   | KINGSLEY AVE<br>ILFRACOMBE<br>DEVON<br>EX34 8ES UNITED KINGDOM  |
| <b>Test specification:</b>  |   |
| Standard .....  | IEC 60601-1:2005 (Third Edition) + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) or IEC 60601-1 (2012 reprint) |
| Test procedure .....  | CB Scheme   |
| Non-standard test method .....  | N/A   |
| Test Report Form No.....  | IEC60601_1J_PS  |
| Test Report Form(s) Originator .....  | UL(US)  |
| Master TRF.....   | 2014-09   |
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**General disclaimer:**

The test results presented in this report relate only to the object tested.  
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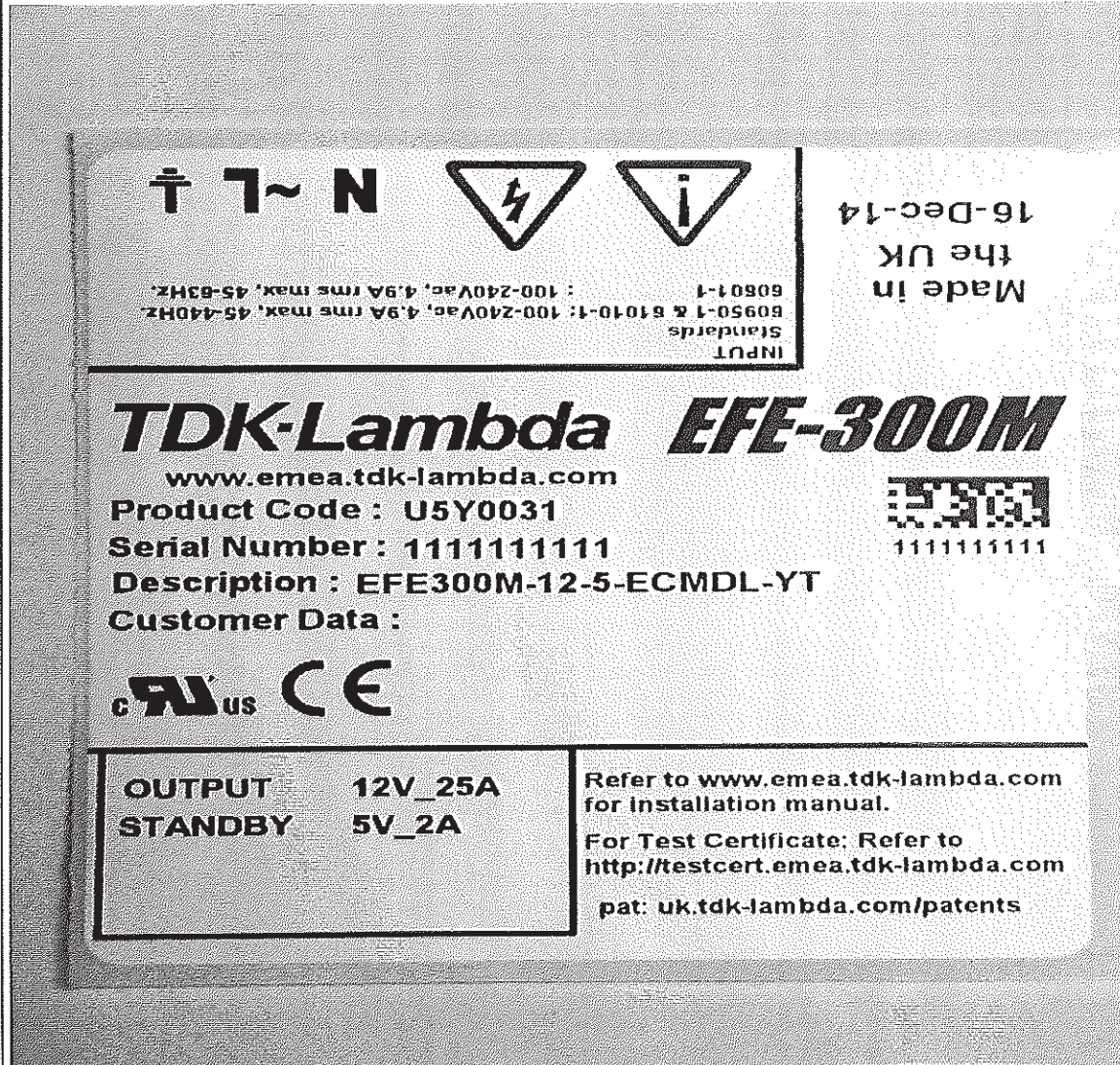
|  |   |  |
|--|---|--|
| Test item description .....  | Medical Switch Mode Power Supply  |  |
| Trade Mark .....   | TDK-Lambda  |  |
|  | <b>TDK-Lambda</b>   |  |
| Manufacturer .....   | TDK-Lambda, Kingsley Avenue, Ilfracombe, Devon, EX34 8ES, United Kingdom                  |  |
| Model/Type reference.....  | EFE300M   |  |
| Ratings.....   | 100-240Vac nom, 4.9A rms max, 45-63Hz.<br>(See Model Differences for details of ratings). |  |
| <b>Testing procedure and testing location:</b>                               |   |  |
| <input type="checkbox"/> CB Testing Laboratory:                              | UL International Demko A/S  |  |
| Testing location/ address .....  | Borupvang 5A, 2750 Ballerup, Denmark  |  |
| <input type="checkbox"/> Associated CB Testing Laboratory:                   |   |  |
| Testing location/ address .....  |   |  |
| Tested by (name + signature).....  |   |  |
| Approved by (name + signature) .....   |   |  |
| <input type="checkbox"/> Testing procedure: TMP/CTF Stage 1:                 |   |  |
| Testing location/ address .....  |   |  |
| Tested by (name + signature).....  |   |  |
| Approved by (name + signature) .....   |   |  |
| <input type="checkbox"/> Testing procedure: WMT/CTF Stage 2:                 |   |  |
| Testing location/ address .....  |   |  |
| Tested by (name + signature).....  |   |  |
| Witnessed by (name + signature) .....  |   |  |
| Approved by (name + signature) .....   |   |  |
| <input checked="" type="checkbox"/> Testing procedure: SMT/CTF Stage 3 or 4: |   |  |
| Testing location/ address .....  | TDK-LAMBDA UK Ltd, Kingsley Avenue, Ilfracombe, EX34 8ES, UK                              |  |
| Tested by (name + signature).....  | N. S. Marsh, S. Hirstwood   |  |

|                                       |                |  |
|---------------------------------------|----------------|--|
| Witnessed by (name + signature) ..... |                |  |
| Approved by (name + signature) .....  | K. P. Tizzard  |  |
| Supervised by (name + signature)..... | Dennis Butcher |  |

|  |                          |
|--|--------------------------|
| <b>List of Attachments (including a total number of pages in each attachment):</b>   |                          |
| National differences (8)<br>Enclosures (95)  |                          |
| <b>Summary of testing</b>  |                          |
| Unless otherwise indicated, all tests were conducted at TDK-LAMBDA UK Ltd, Kingsley Avenue, Ilfracombe, EX34 8ES, UK.  |                          |
| <b>Tests performed (name of test and test clause):</b>   | <b>Testing location:</b> |
| Dielectric Voltage Withstand (8.8.3)   | TDK Lambda UK Ltd        |
| Temperature Test (11)  | Safety Lab               |
| Abnormal Operation (13)  | Kingsley Avenue          |
|  | Ilfracombe               |
|  | North Devon              |
|  | EX34 8ES                 |
| <b>Summary of compliance with National Differences</b>   |                          |
| List of countries addressed: AT, BE, CA, CH, CZ, DE, DK, FI, FR, GB, HU, IL, IT, JP, NL, NO, PL, SE, SI, SK, TR, UA, US  |                          |
| <input checked="" type="checkbox"/> The product fulfils the requirements of IEC 60601-1:2005 + A1:2012. EN60601-1:2006/A12:2014. CAN/CSA-C22.2 No. 60601 (2008), ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10). |                          |

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.



| <b>GENERAL INFORMATION</b>  |   |                                     |        |
|---|---|-------------------------------------|--------|
| <b>Test item particulars (see also Clause 6):</b>   |   |                                     |        |
| Classification of installation and use .....  | For building in   |                                     |        |
| Device type (component/sub-assembly/ equipment/ system):  | Component Switched Mode Power Supply                                  |                                     |        |
| Intended use (Including type of patient, application location) :  | To provide DC power for electronic circuits within medical equipment. |                                     |        |
| Mode of operation .....   | Continuous  |                                     |        |
| Supply connection .....   | Connection to the mains via host equipment                            |                                     |        |
| Accessories and detachable parts included .....   | None  |                                     |        |
| Other options include .....   | None  |                                     |        |
| <b>Testing</b>  |   |                                     |        |
| Date of receipt of test item(s) .....   | 2014-12-03 to 2015-01-05  |                                     |        |
| Dates tests performed .....   | 2014-12-09 to 2015-01-07  |                                     |        |
| <b>Possible test case verdicts:</b>   |   |                                     |        |
| - 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)  |                                     |        |
| <b>Abbreviations used in the report:</b>  |   |                                     |        |
| - normal condition .....  | N.C.  | - single fault condition.....       | S.F.C. |
| - means of Operator protection .....  | MOOP  | - means of Patient protection ..... | MOPP   |
| <b>General remarks:</b>   |   |                                     |        |
| <p>"(See Attachment #)" refers to additional information appended to the report.<br/>                     "(See appended table)" refers to a table appended to the report.<br/>                     The tests results presented in this report relate only to the object tested.<br/>                     This report shall not be reproduced except in full without the written approval of the testing laboratory.<br/>                     List of test equipment must be kept on file and available for review.<br/>                     Additional test data and/or information provided in the attachments to this report.</p> <p>Throughout this report a <input type="checkbox"/> comma / <input checked="" type="checkbox"/> point is used as the decimal separator.</p> <p>This Test Report Form is intended for the investigation of power supplies in accordance with IEC 60601-1:2005, 3<sup>rd</sup> edition + AM1. The Risk Management was excluded from the investigation; this shall be clearly identified in this report and on the accompanying CB Test Certificate.</p> <p>Additional test data and/or information may be provided in the attachments to this report.</p> |   |                                     |        |

**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  Not applicable

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  
 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

1. It is reissue from report# E349607-A34-CB-1 issued on 2014-06-30 by UL International Demko A/S certificate# DK-28859-A1-UL to assess AM1 of 60601-1 3rd Edition.
2. F2, alternative fuse testing, non-critical part (not mains input fuse).
3. Alternative fan testing.
4. Standby voltage 12-13.5V is a range with the nomenclature kept for legacy purposes.
5. Output to Earth assessed for MOPPs.
6. Added two transformer part numbers and drawings.  
 TX1: 230130 is identical to the other TX1 transformers used for standard models but includes an additional comment for Sony models Y5J008# and Y5J015#.  
 TX2: 230129 is identical to the other TX2 transformers used for standard models but includes an additional comment for Sony models Y5J008# and Y5J015#.



**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.

#### Technical Considerations:

- The product was investigated to the following additional standards: EN 60601-1:2006/A12:2014 (Medical electrical equipment Part 1: General requirements for basic safety and essential performance), CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes National Differences for Canada), ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes Deviations for United States)
- 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 following accessories were investigated for use with the product: None
- 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
- The power supply is Class I
- The product is Classified only to the following hazards: Casualty, Fire, Shock
- Software is relied upon for meeting safety requirements related to mechanical, fire and shock: No
- 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 product was assessed for operation at an altitude of 3000m
- Classification of installation and use: Building-in
- The Printed Wiring Board Trace was evaluated for protective earthing/bonding.
- All outputs were evaluated for less than 60Vdc, 42.4Vpk. The applicant has declared the outputs as SELV for voltages up to and including 48V nominal for standard models. Testing has therefore been conducted to ensure compliance with the limits specified in clause 8.4.2(c).
- Risk Management has not been applied to these products.
- Multi-layer PWB's accepted under CBTR Ref. No.: E349607-A23 dated 2014-07-31 and letter Report, Enclosure 8-03 of this report.

#### Engineering Conditions of Acceptability

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

- Insulation separation between: Primary and Secondary is two MOPP's: 408Vrms, 880Vpeak , Insulation separation between: Primary and Earth is one MOPP: 392Vrms, 668Vpeak , Insulation separation between: Secondary and Earth is one MOPP: 240Vrms, 340Vpeak ,
- Branch circuit protection required: 16A (20A For North America and Canada)
- The following outputs are considered SELV: All standard model outputs up to and including 48V nominal. Voltages , above 48V nominal are non-SELV and therefore all outputs become non SELV and must not be , accessible to an operator. ,
- Some PWB mounted components are rated at the minimum coating rating of 125°C
- Consideration should be given to repeating the Earth Leakage Tests in the end use equipment.