Test Report issued under the responsibility of:

TÜVRheinland®

# IEC 60601-1
# Medical electrical equipment
# Part 1: General requirements for basic safety and essential performance

| | |
|---|---|
| **Report Reference No.....:** | **15074095 001** |
| **Date of issue .....:** | 2014-09-28 |
| **Total number of pages.....:** | 133 |
| **CB Testing Laboratory.....:** | TÜV Rheinland (Shanghai) Co., Ltd. |
| **Address .....:** | B1-13/F No.177, Lane 777, West Guangzhong Road, Zhabei District, Shanghai 200072, P.R. China |
| **Applicant's name.....:** | TDK-Lambda Corp. Nagaoka Technical Center |
| **Address .....:** | 2704-1 Settaya-machi, Nagaoka-shi, Niigata 940-1195, Japan |
| **Test specification:** | |
| **Standard .....:** | IEC 60601-1: 2005 + 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 |
| **Test Report Form Originator .....:** | UL(US) |
| **Master TRF .....:** | 2014-07 |

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**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 .....:** | Switching Power Supply (Built-in, Open frame type) |
| **Trade Mark .....:** | TDK·Lambda |
| **Manufacturer.....:** | Same as applicant |
| **Model/Type reference.....:** | MWS65-5, MWS65-12, MWS65-15, MWS65-24, MWS65-48 |
| **Ratings.....:** | MWS65-5:<br>AC input: 100-240V, 1.25A, 50/60Hz<br>DC output: 5V/11A (typical)<br>MWS65-12:<br>AC input: 100-240V, 1.35A, 50/60Hz<br>DC output: 12V/5A (typical)<br>MWS65-15:<br>AC input: 100-240V, 1.35A, 50/60Hz<br>DC output: 15V/4.4A (typical)<br>MWS65-24:<br>AC input: 100-240V, 1.35A, 50/60Hz<br>DC output: 24V/2.8A (typical)<br>MWS65-48:<br>AC input: 100-240V, 1.35A, 50/60Hz<br>DC output: 48V/1.4A (typical) |
| | |

| | | | |
|---|---|---|---|
| **Testing procedure and testing location:** | | | |
| ☒ | **CB Testing Laboratory:** | TÜV Rheinland (Shanghai) Co., Ltd. | |
| **Testing location/ address ..... :** | | B1-13/F No.177, Lane 777, West Guangzhong Road, Zhabei District, Shanghai 200072, P.R. China | |
| ☐ | **Associated CB Testing Laboratory:** | | |
| **Testing location/ address ..... :** | | | |
| **Tested by (name + signature)..... :** | | Angela Lee | |
| **Approved by (name + signature) ..... :** | | Mark Chen | |
| | | | |
| ☐ | **Testing procedure: TMP/CTF Stage 1:** | | |
| **Testing location/ address ..... :** | | | |
| **Tested by (name + signature)..... :** | | | |
| **Approved by (name + signature) ..... :** | | | |
| | | | |
| ☐ | **Testing procedure: WMT/CTF Stage 2:** | | |
| **Testing location/ address ..... :** | | | |
| **Tested by (name + signature)..... :** | | | |
| **Witnessed by (name + signature) ..... :** | | | |
| **Approved by (name + signature) ..... :** | | | |
| | | | |
| ☐ | **Testing procedure: SMT/CTF Stage 3 or 4:** | | |
| **Testing location/ address ..... :** | | | |
| **Tested by (name + signature)..... :** | | | |
| **Witnessed by (name + signature) ..... :** | | | |
| **Approved by (name + signature) ..... :** | | | |
| **Supervised by (name + signature)..... :** | | | |
| | | | |

**List of Attachments (including a total number of pages in each attachment):**

- ATTACHMENT 1 - Photo Documentation (3 pages);
- ATTACHMENT 2 - Technical Documentation (13 pages);
- ATTACHMENT 3 - Measurement Section (18 pages)

**Summary of testing:**

All applicable tests as described throughout this test report and in the Measurement Section were performed.

- Specified ambient temperature for operation is according to manufacturer's specification. (see chart of convection cooling in general information).
- Pre-production samples without serial numbers.
- The load conditions used during testing: Maximum normal load is the operation with the maximum specified DC-load with maximum power condition according to the manufacturer specified.
- The equipment is operated up to 3000m above sea level as declared by manufacturer. Clearances have been evaluated according to IEC 60664-1:1992 table A.2 with a multiplication factor of 1.14 throughout this report.
- Compliance with the requirements of IEC/EN 60601-1-2 (EMC) shall be evaluated for the final system configuration.
- The equipment does not have circuits for direct connection to the patient and not is intended for use in the presence of flammable anaesthetic mixtures with air, oxygen or nitrous oxide.

| **Tests performed (name of test and test clause):** | **Testing location:** |
|---|---|
| • 4.11 Power input<br>• 5.7 Humidity pre-conditioning<br>• 7.1.3 Marking durability<br>• 8.4 Limitation of voltage, current or energy<br>• 8.5.4 Working voltage<br>• 8.7.4 Leakage currents<br>• 8.8.3 Dielectric strength<br>• 11.1 Excessive temperatures<br>• 13 Hazardous situations and fault conditions<br>• 15.5 Mains supply transformers and transformers providing safety isolation | The laboratory described on page 3. |

**Summary of compliance with National Differences**

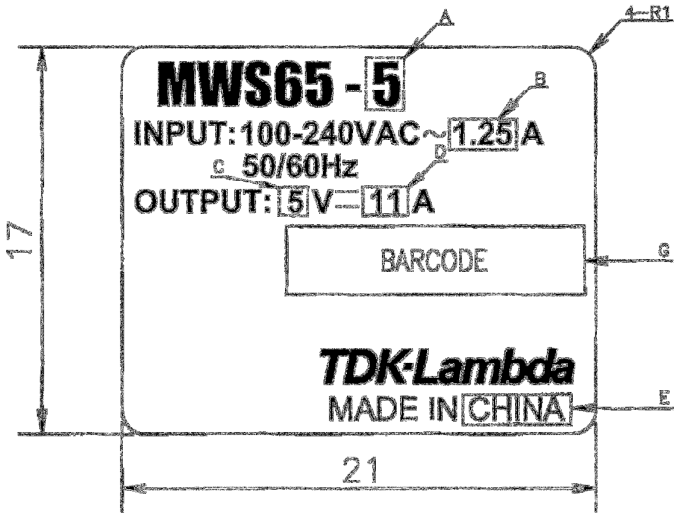
List of countries addressed:

EU Group Differences, EU Special National Conditions

☒ The product fulfils the requirements of EN 60601-1:2006+A11:2011+A1:2013

**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.**




1. MATERIAL YUPO 80 MIC SYNTHETIC PAPER. WHITE (PURCHASED PRINTING)
   PET 50MIC SYNTHETICK PAPER. WHITE (FOR INHOUSE PRINTING SEAL)
2. INK BLACK
3. SAFETY UL, C-UL APPROVAL. TEMPERATURE -40°C TO 100°C
4. LETTERING :

| | FONT | POINT | HEIGHT (mm) |
|---|---|---|---|
| MWS65-5 | IMPACT | 8 | 2.0 |
| INPUT:_, OUTPUT:_ | ARIAL(BOLD) | 4 | 1.0 |
| MADE IN CHINA | ARIAL | 4 | 1.0 |
| TDK-Lambda LOGO | ORIGINAL | | 1.5 |

5. OTHERS

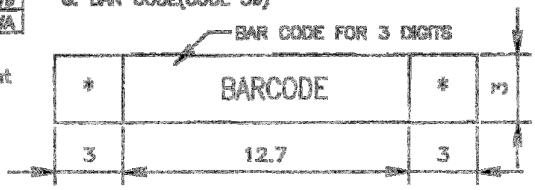
| MODEL | A | B | C | D | G |
|---|---|---|---|---|---|
| MWS65-5 EHFP+ | 5 | 1.25 | 5 | 11 | CW4 |
| MWS65-12 EHFP+ | 12 | 1.35 | 12 | 5 | CW6 |
| MWS65-15 EHFP+ | 15 | 1.35 | 15 | 4.4 | CW8 |
| MWS65-24 EHFP+ | 24 | 1.35 | 24 | 2.8 | CW9 |
| MWS65-48 EHFP+ | 48 | 1.35 | 48 | 1.4 | CWA |

6. RoHS Compliance :
   Refer to T-L Group Green Procurement Guideline : DL-EMS-010_

E: COUNTRY OF MANUFACTURE WILL BE SHOWN. JAPAN or MALAYSIA or CHINA or VIETNAM.

F: BRACKETS IN DOTTED LINES SHOULD NOT APPEAR ON THE FINAL NAME PLATE.

G: BAR CODE(CODE 39)




* NO OTHER MARKING ALLOWED WITHIN 3mm OF BOTH ENDS OF THE BAR CODE.

| GENERAL INFORMATION | |
|---|---|
| **Test item particulars (see also Clause 6):** | |
| Classification of installation and use ..... : | For Class I ME equipment and a built-in, open frame type switching mode power supply |
| Device type (component/sub-assembly/ equipment/ system) : | sub-assembly |
| Intended use (Including type of patient, application location) : | Refer to “General product information” |
| Mode of operation ..... : | Continuous |
| Supply connection ..... : | Primary connector |
| Accessories and detachable parts included..... : | None |
| Other options include ..... : | None |
| **Testing** | |
| Date of receipt of test item(s) ..... : | N/A |
| Dates tests performed ..... : | N/A |
| **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. | - single fault condition..... : S.F.C. |
| - means of Operator protection ..... : MOOP | - means of Patient protection .... : MOPP |
| **General remarks:** | |
| "(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. | |
| **Throughout this report a ☐ comma / ☒ point is used as the decimal separator.** | |

**Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:2012**

| | |
|---|---|
| **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**<br>☐ **Not applicable** |
| **When differences exist; they shall be identified in the General product information section.** | |

**Name and address of factory (ies)..... :** See below

1. Wuxi TDK-Lambda Electronics Co., Ltd.
   No. 6 Xing Chuang Er Lu, Wuxi, Jiangsu 214028, P. R. China
2. TDK-Lambda Malaysia Sdn. Bhd.
   Lot 2 & 3, Batu 9 3/4 Kawasan Perindustrian, Bandar Baru Jaya Gading, 26070 Kuantan Pahang Malaysia
3. Zhangjiagang Hua Yang Electronics Co., Ltd.
   Zhao Feng Industrial Zone, Leyu Town, Zhangjiagang, Jiangsu 215622, P. R. China

History of CB Test Report:

1) Test report No. 15044403 001 and 002 test report were issued for TDK-Lambda Corp. Nagaoka Technical Center. and addressed model mentioned page 1 tested to IEC 60601 1: 2005 + CORR. 1 (2006) + CORR. 2 (2007).
2) Test report No. 15074095 001 This test report issued for TDK-Lambda Corp. Nagaoka Technical Center. serves to combine and upgrade the above mentioned test reports. In this test report updates Group and National Differences. However it is separate CB test report and it does not have to be used in conjunction with any of the previously issued, above mentioned CB test reports.

**General product information:**

The EUTs are a class I open-frame switching mode power supply intended for building-in use in medical electrical equipment.

The equipment employs following PCB:

- PFA-001B (primary, PB and secondary circuits, (double-layers) PCB). The dimension is 102mm x 51mm.

All models are identical except for following differences:

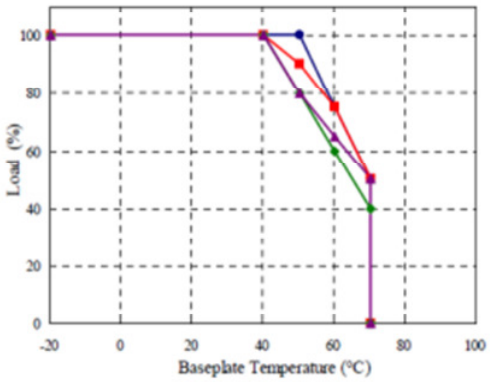
**For rating differences between the models see below tables:**

| Model | Rated input | Minimal output | Rated output (typical) | Maximum output |
|---|---|---|---|---|
| MWS65-5 | AC 100-240V, 1.25A, 50/60Hz | 4.5Vdc | 5Vdc | 5.5Vdc |
| | | 11A | 11A | 10A |
| MWS65-12 | AC 100-240V, 1.35A, 50/60Hz | 10.8Vdc | 12Vdc | 13.2Vdc |
| | | 5A | 5A | 4.55A |
| MWS65-15 | AC 100-240V, 1.35A, 50/60Hz | 13.5Vdc | 15Vdc | 16.5Vdc |
| | | 4.4A | 4.4A | 4A |
| MWS65-24 | AC 100-240V, 1.35A, 50/60Hz | 21.6Vdc | 24Vdc | 26.4Vdc |
| | | 2.8A | 2.8A | 2.55A |
| MWS65-48 | AC 100-240V, 1.35A, 50/60Hz | 43.2Vdc | 48Vdc | 52.8Vdc |
| | | 1.4A | 1.4A | 1.27A |

| Item | MWS65-5 | MWS65-12 | MWS65-15 | MWS65-24 | MWS65-48 |
|---|---|---|---|---|---|
| Secondary E-Capacitor (C51, C52) | 10V, 1800μF max. | 25V, 820μF max. | 25V, 820μF max. | 35V, 560μF max. | 63V, 180μF max. |
| Secondary E-Capacitor (C53) | 10V, 1800μF max. | 25V, 820μF max. | 25V, 820μF max. | Without | Without |
| Secondary E-Capacitor (C54) | 10V, 1800μF | Without | Without | Without | Without |
| Secondary E-Capacitor (C55) | 10V, 1000μF max. | 25V, 560μF max. | 25V, 560μF max. | 35V, 390μF max. | 63V, 100μF max. |

Remark:
Operating temp.: -20ºC to +70ºC (operating temperature depending on equipment's load, mounting position, for details refer to instruction manual).

■ **CONVECTION COOLING**



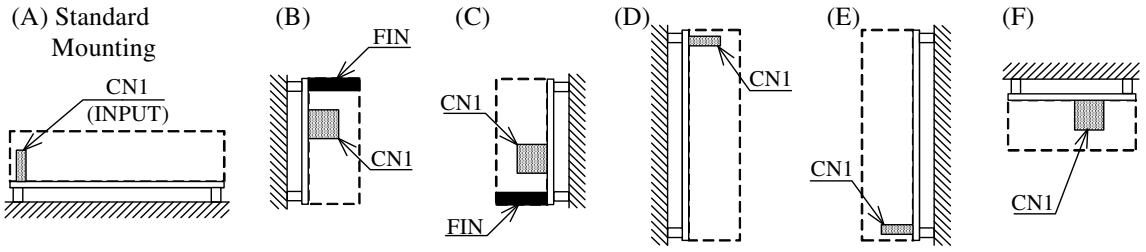

(*1)Output derating is different depending on the output voltage

MOUNTING : (A)-(B) : 5V - 48V
(C) : 12V
(D)-(E) : 12V/48V
MOUNTING : (C) : 5V/15V/24V/48V
(D)-(E) : 15V/24V
MOUNTING : (D)-(E) : 5V
MOUNTING : (F) : 5V - 48V

| Ta(°C) | Load(%) | Load(%) | Load(%) | Load(%) |
|---|---|---|---|---|
| Mounting | A,B,C,D,E | C,D,E | D,E | F |
| -20~40 | 100 | | | |
| 50 | 100 | 90 | 80 | 80 |
| 60 | 75 | 75 | 65 | 60 |
| 70 | 50 | 50 | 50 | 40 |

**Note: Output Derating according to the Mounting Directions:**

Recommended standard mounting method is (A). Method (B)-(F) are also possible. Refer to the output derating below.




**Additional Information**

- This PSU subject to this evaluation is not a medical device or system on its own right, but a component intended for building into such. Risk assessment was therefore not subject of this investigation. It shall be carried out for final medical electrical equipment or system.
- Scope of this PSU evaluation defers the following clauses to be determined as part of the end product:
  Clause 7.2.7 ELECTRICAL INPUT POWER FROM THE SUPPLY MINS,
  Clause 7.5 SAFETY SIGNS,
  Clause 7.6 SYMBOLS,
  Clause 7.9 ACCOMPANYING DOCUMENTS,
  Clause 9 PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS,
  Clause 10 PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS,
  Clause 12 ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS,
  Clause 14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS),
  Clause 16 ME SYSTEMS,
  shall be evaluated in the end device or system.
- The insulation system of the PSU was evaluated for compliance with the MEANS OF OPERATOR PROTECTION (MOOP).
- Compliance with IEC / EN 60601-1-2 shall be evaluated during the end system evaluation.
- The product is for building-in equipment, the overall compliance shall be investigated in the complete medical electrical equipment or system, in particular:
  - Fire enclosure

- Mechanical enclosure
- Electrical enclosure

- Some components are **pre-certified**, which have been evaluated according to the relevant requirements of IEC 60601-1, are employed in this product.
- The equipment does not have circuits for direct connection to the patient and not is intended for use in the presence of flammable anaesthetic mixtures with air, oxygen or nitrous oxide.

Note:
PSU = Power Supply Unit