

Test Report issued under the responsibility of:



# TEST REPORT IEC 60601-1 Part 1: General requirements for basic safety and essential performance

| Report Number                                                                               | 15077117 002                                                                                                         |  |  |  |  |
|---------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|--|--|--|--|
| Date of issue                                                                               | 20.03.2017                                                                                                           |  |  |  |  |
| Total number of pages:                                                                      | 15                                                                                                                   |  |  |  |  |
| Name of Testing Laboratory preparing the Report:                                            | TÜV Rheinland Shanghai Co., Ltd.<br>No.177, 178, Lane 777 West Guangzhong Road, Jing'an District,<br>Shanghai, 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 (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:

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|                                             |              | ing Power Supply                                                                                                    |                                       |  |  |  |
|---------------------------------------------|--------------|---------------------------------------------------------------------------------------------------------------------|---------------------------------------|--|--|--|
| Trade Mark:                                 | <b>TDK·L</b> | Lambda                                                                                                              |                                       |  |  |  |
| Manufacturer :                              | Same a       | as applicant                                                                                                        |                                       |  |  |  |
| Model/Type reference:                       |              | i- <b>zzz/abcde</b> ; CUT75J- <b>zzz/abcde</b><br>522 or 5FF; <b>abcde</b> = any alphanumeric character with "/" or |                                       |  |  |  |
| Ratings:                                    |              | nput: 100-240V, 2.0A, 50-60Hz<br>putput: see page 7 (Table A)                                                       |                                       |  |  |  |
| Testing procedure and testing location      |              |                                                                                                                     |                                       |  |  |  |
| CB Testing Laboratory:                      | 511.         | TÜV Rheinland Shangh                                                                                                | nai Co. I td                          |  |  |  |
| Testing location/ address                   |              |                                                                                                                     | West Guangzhong Road, Jing'an         |  |  |  |
|                                             |              | District, Shanghai, Chin                                                                                            |                                       |  |  |  |
| Associated CB Testing Laborato              | ory:         |                                                                                                                     |                                       |  |  |  |
| Testing location/ address                   | :            |                                                                                                                     |                                       |  |  |  |
| Tested by (name + signature)                | :            | Sunny Sun                                                                                                           | Safet                                 |  |  |  |
| Approved by (name + signature)              | :            | Mark Chen                                                                                                           |                                       |  |  |  |
| Testing procedure: TMP/CTF Sta              | age 1:       |                                                                                                                     |                                       |  |  |  |
| Testing location/ address                   | -            |                                                                                                                     |                                       |  |  |  |
| Tested by (name + signature)                |              |                                                                                                                     |                                       |  |  |  |
| Approved by (name + signature)              |              |                                                                                                                     |                                       |  |  |  |
|                                             |              |                                                                                                                     |                                       |  |  |  |
| Testing procedure: WMT/CTF St               |              |                                                                                                                     |                                       |  |  |  |
| Testing location/ address                   |              |                                                                                                                     | · · · · · · · · · · · · · · · · · · · |  |  |  |
| Tested by (name + signature)                |              |                                                                                                                     |                                       |  |  |  |
| Witnessed by (name + signature)             |              |                                                                                                                     |                                       |  |  |  |
| Approved by (name + signature)              | i            |                                                                                                                     |                                       |  |  |  |
| Testing procedure:<br>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)            | :            |                                                                                                                     | 1                                     |  |  |  |
|                                             |              |                                                                                                                     |                                       |  |  |  |

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| List of Attachments (including a total number of pages in each attachment):<br>N/A<br>Summary of testing:                                                                                                                   |                                                                               |  |  |  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|--|--|--|
|                                                                                                                                                                                                                             |                                                                               |  |  |  |
| No further test is considered necessary.                                                                                                                                                                                    | TÜV Rheinland Shanghai Co., Ltd.                                              |  |  |  |
|                                                                                                                                                                                                                             | No.177, 178, Lane 777 West Guangzhong Road, Jing'an District, Shanghai, China |  |  |  |
| Summary of compliance with National Differences                                                                                                                                                                             |                                                                               |  |  |  |
| List of countries addressed:                                                                                                                                                                                                |                                                                               |  |  |  |
| AT, CA, GB, KR, SE, US                                                                                                                                                                                                      |                                                                               |  |  |  |
| Explanation of used codes:                                                                                                                                                                                                  |                                                                               |  |  |  |
| AT=Austria; CA=Canada; GB=United Kingdom; KR=Koro of America.                                                                                                                                                               | ea of Republic; SE=Sweden; US = United States                                 |  |  |  |
| The product also fulfils the requirements of below:<br>EN 60601-1:2006++A11:2011+A1:2013+A12:2014,<br>ANSI/AAMI ES60601-1:2005+A2 (R2012) +A1,<br>CAN/CSA-C22.2 NO. 60601-1:14 and<br>CAN/CSA-C22.2 NO. 60601-1-08 (R2013). |                                                                               |  |  |  |

## 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.

| <ne< th=""><th>w Models&gt;</th></ne<>                                             | w Models>                          |
|------------------------------------------------------------------------------------|------------------------------------|
| <b>CUT75J- 522</b><br>INPUT: 100-240VAC~ 2.0A                                      | BAR CODE                           |
| 50-60Hz<br>Output: CH1: +5 V== 8.0 A<br>CH2: +12 V == 2.5 A<br>CH3: -12 V == 0.5 A | TDK-Lambda<br>Made in China        |
|                                                                                    |                                    |
| CUT75J- 5FF<br>INPUT: 100-240VAC~ 2,0A<br>50-60Hz                                  | BAR CODE                           |
| OUTPUT: CH1: +5 V 8.0 A<br>CH2: +15 V 8.0 A<br>CH3: -15 V 0.4 A                    | TDK-Lambda<br>Made in China        |
| CUT75J- 522 /A                                                                     |                                    |
| UUT/JJ-JZZ/M<br>INPUT:100-240VAC~2.0A<br>50-60Hz                                   | BAR CODE                           |
| OUTPUT: CH1: +5 V= 8.0 A<br>CH2: +12 V = 2.5 A<br>CH3: -12 V= 0.5 A                | TDK-Lambda<br>Made in China        |
| CUT75J- 5FF/A                                                                      |                                    |
| INPUT: 100-240VAC~ 2.0A<br>50-60Hz                                                 | BAR CODE                           |
| OUTPUT: CH1: +5 V 8.0 A<br>CH2: +15 V == 2.0 A<br>CH3: -15 V == 0.4 A              | <b>TDK-Lambda</b><br>MADE IN CHINA |
| CUT75J- 522 /B<br>Input; 100-240vac~ 2,0a                                          | BAR CODE                           |
| 50-60Hz<br>50-60Hz<br>OUTPUT: CH1: +5 V= 8.0 A<br>CH2: +12 V= 2.5 A                | TDK-Lambda                         |
| CH3; -12 V = 0,5 A                                                                 | MADE IN CHINA                      |
| CUT75J- 5FF/B<br>INPUT: 100-240VAC~ 2.0A<br>50-60Hz                                | BAR CODE                           |
| OUTPUT; CH1; +5 V= 8,0 A<br>CH2; +15 V= 2,0 A                                      | TDK-Lambda<br>Made in China        |



| GENERAL INFORMATION                                             |                                                                                      |
|-----------------------------------------------------------------|--------------------------------------------------------------------------------------|
| Test item particulars (see also Clause 6):                      | For Class I ME equipment and a built-in, open frame type switching mode power supply |
| Classification of installation and use:                         | Fixed                                                                                |
| Device type (component/sub-assembly/ equipment/<br>system)      | Sub-assembly                                                                         |
| Intended use (Including type of patient, application location): | By other methods validated described by the manufacturer                             |
| 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.                                                     |

#### 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  $\Box$  comma /  $\boxtimes$  point is used as the decimal separator.

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.

Additional test data and/or information may be provided in the attachments to this report.

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| Manufacturer's Declaration per sub-clause 4.2.5 of                                                                                                                                                                                                                                                                                                                                  | IECE | E 02:2012                                                               |                         |  |  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|-------------------------------------------------------------------------|-------------------------|--|--|
| The application for obtaining a CB Test Certificate<br>includes more than one factory location and a<br>declaration from the Manufacturer stating that the<br>sample(s) submitted for evaluation is (are)<br>representative of the products from each factory<br>has been provided:<br>When differences exist; they shall be identified in the General product information section. |      |                                                                         |                         |  |  |
| Name and address of factory (ies)                                                                                                                                                                                                                                                                                                                                                   | 1.   | Wuxi TDK-Lambda Ele<br>No. 6 Xing Chuang Er<br>Jiangsu, China           |                         |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                     | 2.   | Zhangjiagang Hua Yar<br>Zhao Feng Industrial Z<br>Zhangjiagang, Jiangsu | Cone, Leyu Town, 215622 |  |  |
| General product information:                                                                                                                                                                                                                                                                                                                                                        |      |                                                                         |                         |  |  |
| Refer to report 15077117 001 for details.                                                                                                                                                                                                                                                                                                                                           |      |                                                                         |                         |  |  |
| Table A for rating differences between the models:                                                                                                                                                                                                                                                                                                                                  |      |                                                                         |                         |  |  |
| Rated Input rating Rated Output                                                                                                                                                                                                                                                                                                                                                     | /1   | Rated Output V2                                                         | Rated Output V3         |  |  |

|                          |                                   | Rate             | ed Input ra  | ating        | Rat            | ed Output         | V1             | Rat            | ed Output         | t V2           | Rat            | ed Output         | V3             |
|--------------------------|-----------------------------------|------------------|--------------|--------------|----------------|-------------------|----------------|----------------|-------------------|----------------|----------------|-------------------|----------------|
| Mode                     | el                                | Input<br>(Va.c.) | Freq<br>(Hz) | Input<br>(A) | Min.<br>output | typical<br>output | Max.<br>output | Min.<br>output | typical<br>output | Max.<br>output | Min.<br>output | typical<br>output | Max.<br>output |
| CUT75-<br>522/abc        | ~~~                               | 100-             | 50-60        | 2.0          | 5.0<br>Vd.c.   | 5.0<br>Vd.c.      | 5.25<br>Vd.c   | +12<br>Vd.c    | +12<br>Vd.c       | +12<br>Vd.c    | -12<br>Vd.c    | -12<br>Vd.c       | -12<br>Vd.c    |
| CUT75J-<br>522/abc       | J- 240 -                          |                  | 2.0          | 8.0A         | 8.0A           | 7.62A             | 2.5A           | 2.5A           | 3.0A              | 0.5A           | 0.5A           | 1.0A              |                |
|                          | Total output power is 76VA max.   |                  |              |              |                |                   |                |                |                   |                |                |                   |                |
| CUT75-<br>5FF/abc        |                                   | 100-             | 50-60        | 2.0          | 5.0<br>Vd.c    | 5.0<br>Vd.c       | 5.25<br>Vd.c   | +15<br>Vd.c    | +15<br>Vd.c       | +15<br>Vd.c    | -15<br>Vd.c    | -15<br>Vd.c       | -15<br>Vd.c    |
| CUT75J- 240<br>5FF/abcde |                                   | 8.0A             | 8.0A         | 7.62A        | 2.0A           | 2.0A              | 2.5A           | 0.4A           | 0.4A              | 1.0A           |                |                   |                |
|                          | Total output power is 77.5VA max. |                  |              |              |                |                   |                |                |                   |                |                |                   |                |

### **Additional Information**

• The input circuit includes one fuse (F1) in the Line conductor and the other fuse (F2) is optional in neutral conductor). Consideration shall be given in the end-use product regarding addition of the second fuse having the same or better characteristics in order to comply with fusing requirements of Clause 8.11.5 of the standard.

#### **Description of change(s):**

- 1. Add new model CUT75J-zzz/abcde
- 2. Re-new critical components list.

For the above described change(s) the following was considered to be necessary:

| Change | Testing | Comments                                                                                                                      |
|--------|---------|-------------------------------------------------------------------------------------------------------------------------------|
| 1      | N/A     | The new model is identical to CUT75- <b>zzz/abcde</b> , no construction differences. No further test is considered necessary. |
| 2      | N/A     | See table 8.10 in bold for details.                                                                                           |

#### Definition of variable(s):

**zzz** = 522 or 5FF;

**abcde** = any alphanumeric character with "/" or blank, non safety relevant information, When all of "a, b, c, d, e" are blank, then "/" is no need. The suffix options example for "a, b, c, d, e" would be used shown below & may be used together (e.g. /TB, /TBCO2).

| Suffix                       | description                     |
|------------------------------|---------------------------------|
| Т                            | Terminal block                  |
| В                            | base plate under PWB            |
| L                            | chassis under PWB               |
| A                            | cover & chassis                 |
| F                            | fix output voltage              |
| Q                            | CQC approval                    |
| other alphanumeric character | non safety relevant information |

#### History of amendments and modifications:

Ref. No. 15077117 001, dated 2015-09-06 (original test report) Ref. No. 15077117 002, dated 2017-03-20 (1<sup>st</sup> Modification)