



Test Report issued under the responsibility of:



**TEST REPORT  
IEC 60601-1**

**Part 1: General requirements for basic safety and essential performance**

Report Number.....: 50326710 001  
Date of issue .....: 2019-12-18  
Total number of pages .....: 156 (excluding attachments, refer to page 3)

Name of Testing Laboratory preparing the Report.....: TÜV Rheinland Shanghai Co., Ltd.  
No.177, 178, Lane 777 West Guangzhong Road, Jing'an District, Shanghai, China

Applicant's name.....: TDK-Lambda (China) Electronics Co., Ltd  
Address .....: No. 95, Zhujiang Road, Xinwu District, 214028 Wuxi, Jiangsu, China

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

**Copyright © 2014 IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE System). All rights reserved.**

This publication may be reproduced in whole or in part for non-commercial purposes as long as the IECEE is acknowledged as copyright owner and source of the material. IECEE takes no responsibility for and will not assume liability for damages resulting from the reader's interpretation of the reproduced material due to its placement and context.

If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed.

**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.**

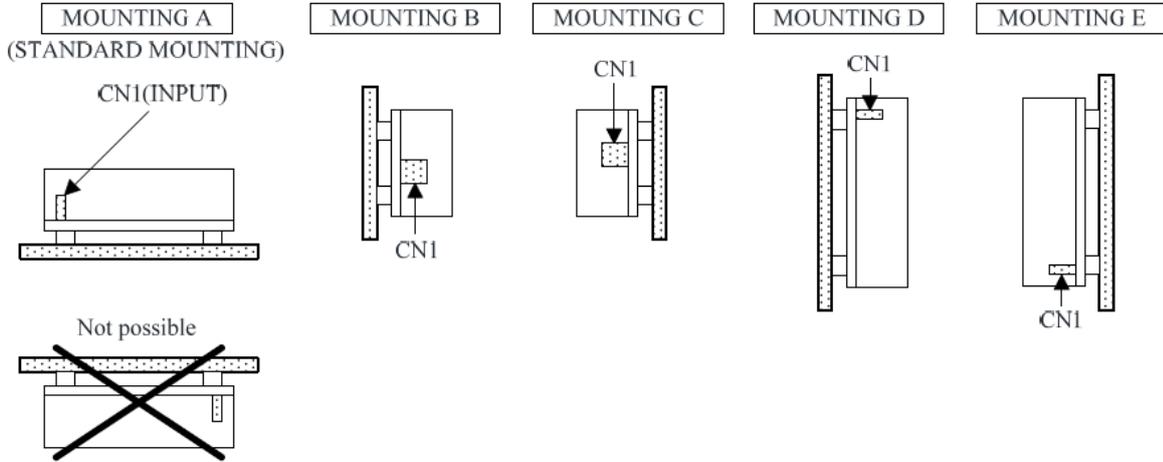
**General disclaimer:**

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.

|  |   |  |
|--|---|--|
| <b>Test item description</b> .....                                       | Switching Power Supply  |  |
| <b>Trade Mark</b> .....  | <b><i>TDK-Lambda</i></b>  |  |
| <b>Manufacturer</b> .....  | Same as applicant   |  |
| <b>Model/Type reference</b> .....  | CUS600My-zxxxxxxx, CME600Ay-zxxxxxxx<br>(y = blank; z = 12, 19, 24, 28, 32, 36 or 48; xxxxxxx = /ADJ, /T, /J, /M, /C, /C2, /SF, /G, /EF, other alphanumeric character, symbol or blank)<br>Refer to page 14 for definition of variables |  |
| <b>Ratings</b> .....   | AC input: 100-240V, 50-60Hz, 4.5A or 7.0A<br>DC output: See the model list on pages 10-12 for details   |  |
| <b>Testing procedure and testing location:</b>                           |   |  |
| <input checked="" type="checkbox"/> <b>CB Testing Laboratory:</b>        | TÜV Rheinland Shanghai Co., Ltd.  |  |
| <b>Testing location/ address</b> ..... :                                 | No.177, 178, Lane 777 West Guangzhong Road, Jing'an District, Shanghai, China   |  |
| <input type="checkbox"/> <b>Associated CB Testing Laboratory:</b>        |   |  |
| <b>Testing location/ address</b> ..... :                                 |   |  |
| <b>Tested by (name + signature)</b> ..... :                              | Sunny Sun<br>(Technical Expert)   |  |
| <b>Approved by (name + signature)</b> .....                              | Mark Chen<br>(Technical Reviewer)   |  |
| <b>Testing procedure: TMP/CTF Stage 1:</b>                               |   |  |
| <input type="checkbox"/> <b>Testing procedure: TMP/CTF Stage 1:</b>      |   |  |
| <b>Testing location/ address</b> ..... :                                 |   |  |
| <b>Tested by (name + signature)</b> ..... :                              |   |  |
| <b>Approved by (name + signature)</b> .....                              |   |  |
| <b>Testing procedure: WMT/CTF Stage 2:</b>                               |   |  |
| <input type="checkbox"/> <b>Testing procedure: WMT/CTF Stage 2:</b>      |   |  |
| <b>Testing location/ address</b> ..... :                                 |   |  |
| <b>Tested by (name + signature)</b> ..... :                              |   |  |
| <b>Witnessed by (name + signature)</b> .....                             |   |  |
| <b>Approved by (name + signature)</b> .....                              |   |  |
| <b>Testing procedure: SMT/CTF Stage 3 or 4:</b>                          |   |  |
| <input type="checkbox"/> <b>Testing procedure: SMT/CTF Stage 3 or 4:</b> |   |  |
| <b>Testing location/ address</b> ..... :                                 |   |  |
| <b>Tested by (name + signature)</b> ..... :                              |   |  |
| <b>Witnessed by (name + signature)</b> .....                             |   |  |
| <b>Approved by (name + signature)</b> .....                              |   |  |
| <b>Supervised by (name + signature)</b> ..... :                          |   |  |

|  |  |
|--|--|
| <p><b>List of Attachments (including a total number of pages in each attachment):</b><br/> ATTACHMENT – Measurement Section (5 pages)<br/> ATTACHMENT – National Differences (14 pages)<br/> ATTACHMENT – Photo documentation (12 pages)<br/> Note: Total number of pages in each attachment is indicated in individual attachment.</p>  |  |
| <p><b>Summary of testing:</b></p>  |  |
| <p><b>Tests performed (name of test and test clause):</b></p>  | <p><b>Testing location:</b></p>  |
| <p>This CB re-issue test report is based on the previous test report 50271613 001, with the certificate no.: DE 2-025606 with following changes:</p> <ol style="list-style-type: none"> <li>1. Change Applicant and Manufacturer from WUXI TDK-LAMBDA ELECTRONICS CO LTD to TDK-Lambda (China) Electronics Co., Ltd.</li> <li>2. Add additional new factory TDK-Lambda (China) Electronics Co., Ltd.</li> <li>3. Add additional description of peak power.</li> <li>4. Update critical components list for alternate sources.</li> <li>5. Slightly increase 1.5 mm and 1 mm for case and studs respectively for model with suffix /EF.</li> <li>6. The DC fan wire moves from the outside of the insulator to the inside of the insulator for model with suffix /EF.</li> <li>7. Change maximum operation temperature of X-Cap (C1) source form 100°C to 110°C.</li> <li>8. Minor change in circuitry as well as PCB layout.</li> <li>9. Update National Difference acc. to CB Scheme rule.</li> </ol> <p>All applicable tests as described in Test Case and Measurement Sections were performed on models CUS600M-12, CUS600M-19, CUS600M-28, CUS600M-32 and CUS600M-48 to represent others. The maximum specified operation ambient temperature is 70°C. Specified ambient temperature for operation is according to manufacturer's specification. (see chart of convection cooling and Forced air cooling on following pages).<br/> The load conditions used during testing: Maximum normal load for this equipment is the operation with the maximum specified DC-load with maximum power condition according to the manufacturer specified.<br/> Mounting Direction: Mounting A and B be used to represent others.<br/> Air speed is same between EUT with EF construction and forced air cooling condition, and select EF construction for temperature testing covered forced air cooling condition.<br/> The test samples are pre-production without serial numbers.</p> <p><b>Uncertainty:</b><br/> When determining for test conclusion, measurement uncertainty of tests has been considered.<br/> The determination of the test conclusion is based on IEC Guide 115 in consideration of measurement uncertainty.</p> | <p>TÜV Rheinland Shanghai Co., Ltd.<br/> No.177, 178, Lane 777 West<br/> Guangzhong Road, Jing'an District,<br/> Shanghai, China</p> |

**MOUNTING DIRECTIONS**

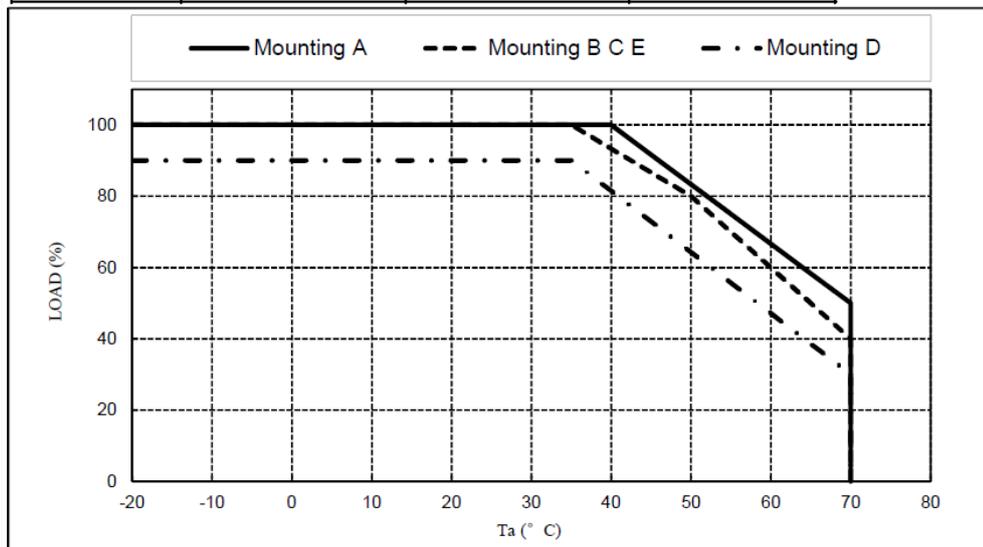


**Derating Curve:**

**Convection cooling condition:**

Condition A: Main output is derating according the following, standby mode power is no load.

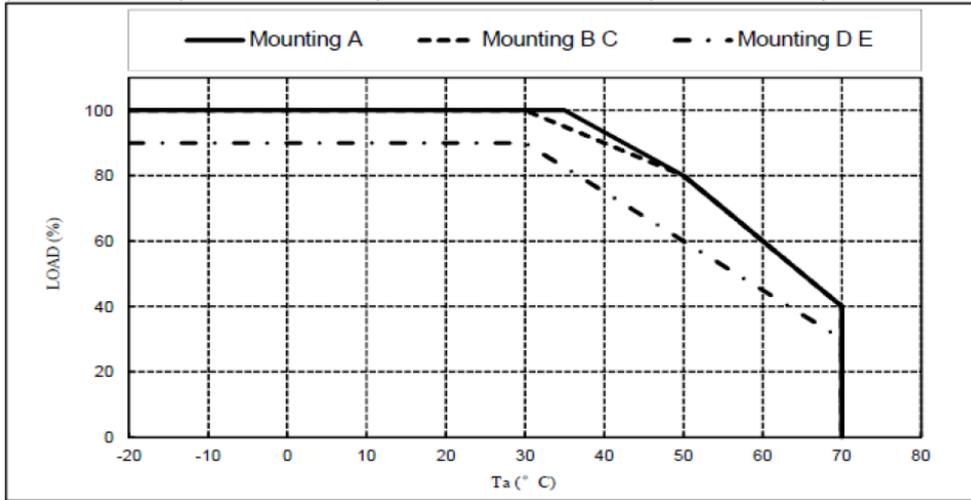
| Ta (°C)   | Mounting A | Mounting B C E | Mounting D |
|-----------|------------|----------------|------------|
|           | LOAD (%)   | LOAD (%)       | LOAD (%)   |
| -20 - +35 | 100        | 100            | 90         |
| 40        | 100        | 93.3           | 81.4       |
| 50        | 83.3       | 80             | 64.3       |
| 60        | 66.7       | 60             | 47.1       |
| 70        | 50         | 40             | 30         |



Condition B: Main output and standby mode power is derating according the following.

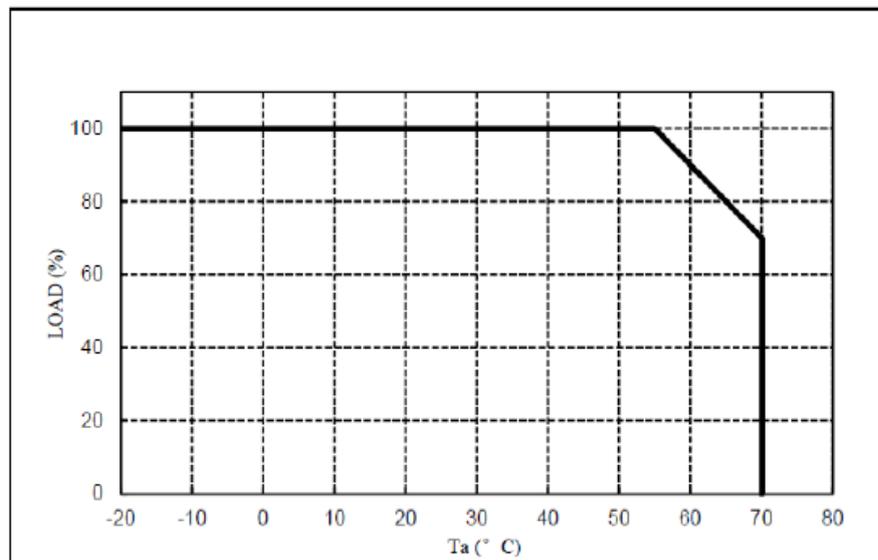
MODEL: ALL MODELS

| Ta (°C)   | Mounting A | Mounting B C | Mounting D E |
|-----------|------------|--------------|--------------|
|           | LOAD (%)   | LOAD (%)     | LOAD (%)     |
| -20 - +30 | 100        | 100          | 90           |
| 35        | 100        | 95           | 82.5         |
| 40        | 93.3       | 90           | 75           |
| 50        | 80         | 80           | 60           |
| 60        | 60         | 60           | 45           |
| 70        | 40         | 40           | 30           |



**Forced air cooling condition:**

| Ta (°C)   | LOAD (%) |
|-----------|----------|
| -20 - +55 | 100      |
| 60        | 93.4     |
| 70        | 70       |



**Summary of compliance with National Differences:**

List of countries addressed:

CA, US

Explanation of used codes:

CA = Canada; US = United States of America

Note(s):

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

**The product fulfils the requirements of**

IEC 60601-1:2005 (Third Edition) + AM1 (2012)

**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.

<Representative>

**Marking for CUS600M series**

**CUS600M - 12**  
**INPUT : 100 - 240VAC ~ 7.0 A**  
**50 - 60Hz**  
**OUTPUT : 12 V $\overline{\text{---}}$  50 A**




EHFP

**TDK·Lambda**  
 MADE IN CHINA

**CUS600M - 19**  
**INPUT : 100 - 240VAC ~ 7.0 A**  
**50 - 60Hz**  
**OUTPUT : 19 V $\overline{\text{---}}$  31.6 A**




EHFP

**TDK·Lambda**  
 MADE IN CHINA

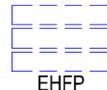
**CUS600M - 24**  
**INPUT : 100 - 240VAC ~ 7.0 A**  
**50 - 60Hz**  
**OUTPUT : 24 V $\overline{\text{---}}$  25 A**




EHFP

**TDK·Lambda**  
 MADE IN CHINA

**CUS600M - 28**  
**INPUT : 100 - 240VAC ~ 7.0 A**  
**50 - 60Hz**  
**OUTPUT : 28 V $\overline{\text{---}}$  21.5 A**




EHFP

**TDK·Lambda**  
 MADE IN CHINA

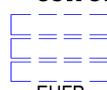
**CUS600M - 32**  
**INPUT : 100 - 240VAC ~ 7.0 A**  
**50 - 60Hz**  
**OUTPUT : 32 V $\overline{\text{---}}$  18.8 A**




EHFP

**TDK·Lambda**  
 MADE IN CHINA

**CUS600M - 36**  
**INPUT : 100 - 240VAC ~ 7.0 A**  
**50 - 60Hz**  
**OUTPUT : 36 V $\overline{\text{---}}$  16.7 A**




EHFP

**TDK·Lambda**  
 MADE IN CHINA

**CUS600M - 48**  
**INPUT : 100 - 240VAC ~ 7.0 A**  
**50 - 60Hz**  
**OUTPUT : 48 V $\overline{\text{---}}$  12.6 A**




EHFP

**TDK·Lambda**  
 MADE IN CHINA

Cont.

## Marking for CME600A series

**CME600A-12**  
**INPUT : 100 - 240VAC ~ 7.0 A**  
**50 - 60Hz**  
**OUTPUT : 12 V $\overline{\text{---}}$  50 A**




**TDK-Lambda**  
 MADE IN CHINA

**CME600A - 19**  
**INPUT : 100 - 240VAC ~ 7.0 A**  
**50 - 60Hz**  
**OUTPUT : 19 V $\overline{\text{---}}$  31.6 A**



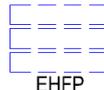

**TDK-Lambda**  
 MADE IN CHINA

**CME600A - 24**  
**INPUT : 100 - 240VAC ~ 7.0 A**  
**50 - 60Hz**  
**OUTPUT : 24 V $\overline{\text{---}}$  25 A**




**TDK-Lambda**  
 MADE IN CHINA

**CME600A - 28**  
**INPUT : 100 - 240VAC ~ 7.0 A**  
**50 - 60Hz**  
**OUTPUT : 28 V $\overline{\text{---}}$  21.5 A**




**TDK-Lambda**  
 MADE IN CHINA

**CME600A - 32**  
**INPUT : 100 - 240VAC ~ 7.0 A**  
**50 - 60Hz**  
**OUTPUT : 32 V $\overline{\text{---}}$  18.8 A**




**TDK-Lambda**  
 MADE IN CHINA

**CME600A - 36**  
**INPUT : 100 - 240VAC ~ 7.0 A**  
**50 - 60Hz**  
**OUTPUT : 36 V $\overline{\text{---}}$  16.7 A**




**TDK-Lambda**  
 MADE IN CHINA

**CME600A - 48**  
**INPUT : 100 - 240VAC ~ 7.0 A**  
**50 - 60Hz**  
**OUTPUT : 48 V $\overline{\text{---}}$  12.6 A**




**TDK-Lambda**  
 MADE IN CHINA

Remark: The rating labels of all models have the same design except for the model designation.

| <b>GENERAL INFORMATION</b>  |  |
|---|--|
| <b>Test item particulars (see also Clause 6):</b>   | For not classified 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/ 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   |
| <b>Testing</b>  |  |
| Date of receipt of test item(s) .....   | 2019-06-01 (report no.: 50271613 001)<br>2019-12-05 (report no.: 50326710 001)               |
| Dates tests performed.....  | 2019-06-01 to 2019-07-19 (report no.: 50271613 001)<br>2019-12-16 (report no.: 50326710 001) |
| <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 .....   |
| - means of Operator protection .....  | - means of Patient protection ...  |
|   |  |
| <b>General remarks:</b>   |  |
| "(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.   |  |
| <b>Throughout this report a <input type="checkbox"/> comma / <input checked="" type="checkbox"/> point is used as the decimal separator.</b>  |  |
| 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.  |  |

| Manufacturer's Declaration per sub-clause 4.2.5 of IEC60061-1:2012   |                   |           |                 |                          |   |                        |                |
|--|-------------------|-----------|-----------------|--------------------------|---|------------------------|----------------|
| <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><input checked="" type="checkbox"/> Yes<br/><input type="checkbox"/> Not applicable</p>   |                   |           |                 |                          |   |                        |                |
| <p>When differences exist; they shall be identified in the General product information section.</p>  |                   |           |                 |                          |   |                        |                |
| <p>Name and address of factory (ies)..... :</p> <ol style="list-style-type: none"> <li>1. TDK-Lambda (China) Electronics Co., Ltd.<br/>No. 6 Xing Chuang Er Lu 214028 Wuxi Jiangsu China</li> <li>2. Zhangjiagang Hua Yang Electronics Co., Ltd.<br/>Zhao Feng Industrial Zone, Leyu Town 215622 Zhangjiagang, Jiangsu, China</li> <li>3. TDK-Lambda (China) Electronics Co., Ltd.<br/>No. 95, Zhujiang Road, Xinwu District, 214028 Wuxi Jiangsu, China</li> </ol>  |                   |           |                 |                          |   |                        |                |
| <p><b>General product information:</b></p> <p>The PSU is a component type switching mode power supplies intended for the earthed construction or non-earthed construction of medical equipment.</p> <ul style="list-style-type: none"> <li>- For earthed construction (Class I), the PSU need to be reliably earthed and professionally installed and fixed with metal screws.</li> <li>- For non-earthed construction (Class II), no earthing connection is required. The PSU need to be fixed so, that it is insulated from any unearthed accessible conductive part by reinforced insulation.</li> </ul> <p>Model CME600Ay-zxxxxxxx is identical to model CUS600My-zxxxxxxx except for model name.</p> <p>All models are identical, except for the optional chassis, cover, turns of Transformer and the rating of some components which results in different output ratings. See Model List below for details.</p> |                   |           |                 |                          |   |                        |                |
| <p><b>For rating differences between the models see below tables:</b></p>  |                   |           |                 |                          |   |                        |                |
| Series Model   | I/p voltage (Vac) | Freq (Hz) | I/p current (A) | Output Channel           | Minimal output  | Rated output (typical) | Maximum output |
| <b>Convection cooling condition</b>  |                   |           |                 |                          |   |                        |                |
| CUS600My-12xxxxxxx<br>CME600Ay-12xxxxxxx   | 100-240           | 50-60     | 4.5             | Main output              | 10.8Vdc   | 12Vdc                  | 12.9Vdc        |
|  |                   |           |                 |                          | 10.8Vdc – 12.9Vdc<br>Normal Rating: 33.4A, 400.8W Max.<br>Peak Rating: 50A, 600W Max. (Dynamic)     |                        |                |
|  |                   |           |                 | Standby power (Optional) | 5Vdc (Rated)  |                        |                |
|  |                   |           |                 |                          | 2A (Rated)  |                        |                |
| CUS600My-19xxxxxxx<br>CME600Ay-19xxxxxxx   | 100-240           | 50-60     | 4.5             | Main output              | 17.1Vdc   | 19Vdc                  | 20.5Vdc        |
|  |                   |           |                 |                          | 17.1Vdc – 20.5Vdc<br>Normal Rating: 21.1A, 400.9W Max.<br>Peak Rating: 31.6A, 600.4W Max. (Dynamic) |                        |                |
|  |                   |           |                 | Standby power (Optional) | 5Vdc (Rated)  |                        |                |
|  |                   |           |                 |                          | 2A (Rated)  |                        |                |

|   |         |       |     |                          |  |        |          |
|---|---------|-------|-----|--------------------------|--|--------|----------|
| CUS600My-24xxxxxxx<br>CME600Ay-24xxxxxxx  | 100-240 | 50-60 | 4.5 | Main output              | 21.6Vdc  | 24Vdc  | 25.9Vdc  |
|   |         |       |     |                          | 21.6Vdc – 25.9Vdc,<br>Normal Rating: 16.7A, 400.8W Max.<br>Peak Rating: 25A, 600W Max. (Dynamic)     |        |          |
|   |         |       |     | Standby power (Optional) | 5Vdc (Rated)   |        |          |
|   |         |       |     |                          | 2A (Rated)   |        |          |
| CUS600My-28xxxxxxx<br>CME600Ay-28xxxxxxx  | 100-240 | 50-60 | 4.5 | Main output              | 25.2Vdc  | 28Vdc  | 30.2Vdc  |
|   |         |       |     |                          | 25.2Vdc – 30.2Vdc,<br>Normal Rating: 14.3A, 400.4W Max.<br>Peak Rating: 21.5A, 602W Max. (Dynamic)   |        |          |
|   |         |       |     | Standby power (Optional) | 5Vdc (Rated)   |        |          |
|   |         |       |     |                          | 2A (Rated)   |        |          |
| CUS600My-32xxxxxxx<br>CME600Ay-32xxxxxxx  | 100-240 | 50-60 | 4.5 | Main output              | 28.8Vdc  | 32Vdc  | 34.5Vdc  |
|   |         |       |     |                          | 28.8Vdc – 34.5Vdc,<br>Normal Rating: 12.5A, 400W Max.<br>Peak Rating: 18.8A, 601.6W Max. (Dynamic)   |        |          |
|   |         |       |     | Standby power (Optional) | 5Vdc (Rated)   |        |          |
|   |         |       |     |                          | 2A (Rated)   |        |          |
| CUS600My-36xxxxxxx<br>CME600Ay-36xxxxxxx  | 100-240 | 50-60 | 4.5 | Main output              | 32.4Vdc  | 36Vdc  | 38.8Vdc  |
|   |         |       |     |                          | 32.4Vdc – 38.8Vdc,<br>Normal Rating: 11.1A, 399.6W Max.<br>Peak Rating: 16.7A, 601.2W Max. (Dynamic) |        |          |
|   |         |       |     | Standby power (Optional) | 5 Vdc (Rated)  |        |          |
|   |         |       |     |                          | 2 A (Rated)  |        |          |
| CUS600My-48xxxxxxx<br>CME600Ay-48xxxxxxx  | 100-240 | 50-60 | 4.5 | Main output              | 43.2 Vdc   | 48 Vdc | 51.8 Vdc |
|   |         |       |     |                          | 43.2Vdc – 51.8Vdc,<br>Normal Rating: 8.4A, 403.2W Max,<br>Peak Rating: 12.6A, 604.8W Max. (Dynamic)  |        |          |
|   |         |       |     | Standby power (Optional) | 5 Vdc (Rated)  |        |          |
|   |         |       |     |                          | 2A (Rated)   |        |          |
| <b>Forced air cooling condition (airflow: air velocity 2.7m/s &amp; air volume 28.6CFM)</b> |         |       |     |                          |  |        |          |
| CUS600My-12xxxxxxx<br>CME600Ay-12xxxxxxx  | 100-240 | 50-60 | 7.0 | Main output              | 10.8Vdc  | 12Vdc  | 12.9Vdc  |
|   |         |       |     |                          | 50A  | 50A    | 46.6A    |
|   |         |       |     | Standby power (Optional) | 5Vdc (Rated)   |        |          |
|   |         |       |     |                          | 2A (Rated)   |        |          |
| CUS600My-19xxxxxxx  | 100-240 | 50-60 | 7.0 | Main output              | 17.1Vdc  | 19Vdc  | 20.5Vdc  |
|   |         |       |     |                          | 31.6A  | 31.6A  | 29.3A    |

|   |         |       |     |                          |                  |                |                  |
|---|---------|-------|-----|--------------------------|------------------|----------------|------------------|
| CME600Ay-19xxxxxxx  |         |       |     | Standby power (Optional) | 5Vdc (Rated)     |                |                  |
|   |         |       |     |                          | 2A (Rated)       |                |                  |
| CUS600My-24xxxxxxx<br>CME600Ay-24xxxxxxx  | 100-240 | 50-60 | 7.0 | Main output              | 21.6Vdc<br>25A   | 24Vdc<br>25A   | 25.9Vdc<br>23.2A |
|   |         |       |     | Standby power (Optional) | 5Vdc (Rated)     |                |                  |
|   |         |       |     |                          | 2A (Rated)       |                |                  |
| CUS600My-28xxxxxxx<br>CME600Ay-28xxxxxxx  | 100-240 | 50-60 | 7.0 | Main output              | 25.2Vdc<br>21.5A | 28Vdc<br>21.5A | 30.2Vdc<br>20.0A |
|   |         |       |     | Standby power (Optional) | 5Vdc (Rated)     |                |                  |
|   |         |       |     |                          | 2A (Rated)       |                |                  |
| CUS600My-32xxxxxxx<br>CME600Ay-32xxxxxxx  | 100-240 | 50-60 | 7.0 | Main output              | 28.8Vdc<br>18.8A | 32Vdc<br>18.8A | 34.5Vdc<br>17.5A |
|   |         |       |     | Standby power (Optional) | 5Vdc (Rated)     |                |                  |
|   |         |       |     |                          | 2A (Rated)       |                |                  |
| CUS600My-36xxxxxxx<br>CME600Ay-36xxxxxxx  | 100-240 | 50-60 | 7.0 | Main output              | 32.4Vdc<br>16.7A | 36Vdc<br>16.7A | 38.8Vdc<br>15.5A |
|   |         |       |     | Standby power (Optional) | 5Vdc (Rated)     |                |                  |
|   |         |       |     |                          | 2A (Rated)       |                |                  |
| CUS600My-48xxxxxxx<br>CME600Ay-48xxxxxxx  | 100-240 | 50-60 | 7.0 | Main output              | 43.2Vdc<br>12.6A | 48Vdc<br>12.6A | 51.8Vdc<br>11.7A |
|   |         |       |     | Standby power (Optional) | 5Vdc (Rated)     |                |                  |
|   |         |       |     |                          | 2A (Rated)       |                |                  |
| Remark:<br>Operating temp.: up to +70°C (operating temperature depending on equipment's load, mounting position, for details refer to instruction manual). / EF the standby current (2A) is including the fan current (0.3A). |         |       |     |                          |                  |                |                  |

#### 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.
- The insulation system of the PSU was evaluated for compliance with the **MEANS OF PATIENT PROTECTION (MOPP)**.
- 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 anesthetic mixtures with air, oxygen or nitrous oxide.
- The input circuit includes one fuse (F1A) in the Line conductor and the other fuse (F1B) 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.
- The metal enclosure of Class II equipment should be evaluated by end system.
- Recommend by manufacturer as below:

The components listed in the following table must not exceed the temperatures given. To determine the component temperatures the heating test must be conducted in accordance with the requirements of the standard in question. Consideration should also be given to the requirements of other safety standards. Test requirements include: PSU to be fitted in its end-use equipment and operated under the most adverse conditions permitted in the end-use equipment handbook/specification and which will result in the highest temperatures in the PSU. To determine the most adverse conditions consideration should be given to the end use equipment maximum operating ambient, the PSU loading and input voltage, ventilation, end use equipment orientation, the position of doors & covers etc. Temperatures should be monitored using type K fine wire thermocouples (secured with cyanoacrylate adhesive or similar) placed on the hottest part of the component (out of any direct airflow) and the equipment should be run until all temperatures have stabilized.

| Circuit Ref.                      | Description                 | Max. Temperature (°C)                      |
|-----------------------------------|-----------------------------|--|
| CN1                               | Input Connector             | 105  |
| C1                                | X Capacitor                 | 110  |
| L2                                | Common Mode Choke Winding   | 130  |
| C5,C52                            | Y Capacitor                 | 125  |
| BD1                               | Bridge Diode                | 150  |
| L4                                | Boost Choke Winding         | 155  |
| C6                                | Boost Capacitor             | 105  |
| Q1                                | Boost FET                   | 150  |
| T1                                | Main Transformer Winding    | 130  |
| T2                                | Standby Transformer Winding | 130  |
| PC103,PC106                       | Opto-Coupler                | 110  |
| C51A,C51B,C51C,<br>C51D,C51E,C51F | Electrolytic Capacitors     | 105 (12V,32V,36V,48V)<br>125 (19V,24V,28V) |
| C61                               | Electrolytic Capacitor      | 105  |

Note:

PSU = Power Supply Unit

**Definition of variable(s):**

CUS600My-zxxxxxxx , CME600Ay-zxxxxxxx

(y = blank; z = 12, 19, 24, 28, 32, 36 or 48; xxxxxxx = /ADJ, /T, /J, /M, /C, /C2, /SF, /G, /EF, other alphanumeric character, symbol or blank)

| Variable:                            | Range of variable:  | Content:                                       |
|--------------------------------------|---|--|
| <b>y</b>                             | blank   | -  |
| <b>z</b>                             | 12, 19, 24, 28, 32, 36 or 48  | Denoting output voltage from 12 Vdc to 48 Vdc. |
| <b>xxxxxxx</b>                       | blank   | Denoting for Standard model                    |
|                                      | /ADJ  | Denoting output adjustable                     |
|                                      | /T  | Denoting terminal block connector              |
|                                      | /J  | Denoting JST connector                         |
|                                      | /M  | Denoting molex connector                       |
|                                      | /C  | Denoting single side PWB coating               |
|                                      | /C2   | Denoting double side PWB coating               |
|                                      | /SF   | Denoting single fuse                           |
|                                      | /G  | Denoting low earth leakage current             |
|                                      | /EF   | Denoting end fan                               |
| other alphanumeric character, symbol | Used for market purposes, no construction differences and no safety impact. |  |

1. Scope of Power Supply evaluation defers the following clauses to be determined as part of the end product investigation:

- 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,
- Risk Management was excluded from this investigation

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

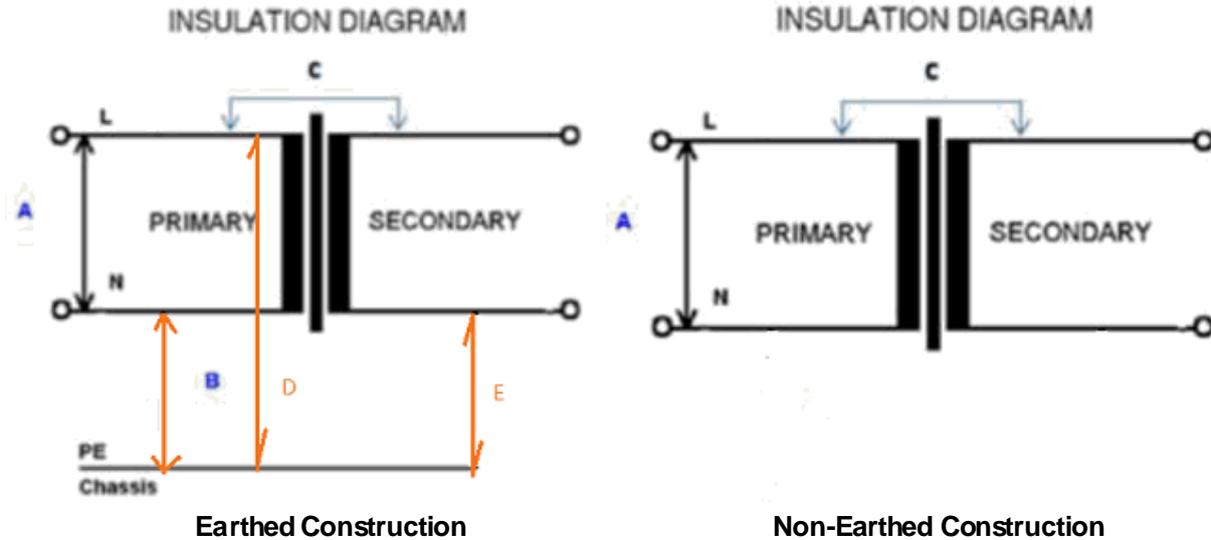
For use only in or with complete equipment where the acceptability of the combination is determined by the CB Testing Laboratory, when installed in an end-product, consideration must be given to the following:

- For Power Supplies with No RM: End product Risk Management Process to include consideration of requirements specific to the Power Supply.
- For Power Supplies with No RM: End product Risk Management Process to consider the acceptability of risk for the following components that were identified as High-Integrity Component: i.e. Fuse (F1A).
- For Power Supplies with No RM: End product Risk Management Process to consider the need

for simultaneous fault condition testing.

- For Power Supplies with No RM: End product Risk Management Process to consider the need for different orientations of installation during testing.
- For Power Supplies with No RM with Exposure Condition outside of Humidity Range: Power Supply tested in 40°C, 95%RH. End product Risk Management Process to determine risk acceptability criteria.
- For Power Supplies with No RM and Insulating Materials: End product to determine the acceptability of risk in conjunction to insulation to resistance to heat, moisture, and dielectric strength.
- For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the movement of components as part of the power supply.
- For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the movement of conductors as part of the power supply.
- For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the routing of wires away from moving parts and sharp edges as part of the power supply.
- For Power Supplies with No RM and Not tested with Test Corner: Temperature Test was conducted without Test Corner. End product to determine the acceptability of risk in conjunction to temperature testing without test corner as part of the power supply.
- For Power Supplies with No RM or Units without Cleaning/Disinfection Methods: End product to determine the acceptability of risk in conjunction to the Cleaning and Disinfection Methods as part of the power supply.
- For Power Supplies with No RM or Units with Liquids: End product to determine the acceptability of risk in conjunction to the Leakage of Liquids as part of the power supply.
- For Power Supplies with No RM or Units with Indicators: End product to determine the acceptability of risk in conjunction to the Arrangement of Indicators as part of the power supply.
- For Power Supplies with No RM or Units with Enclosures: End product to determine the acceptability of risk in conjunction to the results of Mechanical Testing conducted as part of the power supply
- For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the selection of components as it pertains to the intended use, essential performance, transport, storage conditions as part of the power supply
- For Power Supplies with Thermal Cut-off and No RM: End product to determine the acceptability of risk in conjunction to the use of Thermal Cut-off and Overcurrent releases as part of the power supply
- For Power Supplies with Pre-set components and No RM: End product to determine the acceptability of risk in conjunction to the use of Pre-set controls as part of the power supply.

| IEC 60601-1 |                    |                 |         |
|-------------|--------------------|-----------------|---------|
| Clause      | Requirement + Test | Result - Remark | Verdict |



| TABLE: INSULATION DIAGRAM                                     |  |   |                  |                              |                        |                                     |                        |                         | Pass                                     |
|---|--|---|------------------|------------------------------|------------------------|-------------------------------------|------------------------|-------------------------|--|
| Pollution degree .....  |  | 2   |                  |                              |                        |                                     |                        |                         | —  |
| Overvoltage category .....                                    |  | II  |                  |                              |                        |                                     |                        |                         | —  |
| Altitude .....  |  | 5000  |                  |                              |                        |                                     |                        |                         | —  |
| Additional details on parts considered as applied parts ..... |  | <input checked="" type="checkbox"/> None <input type="checkbox"/> Areas _____ |                  | (See Clause 4.6 for details) |                        |                                     |                        |                         | —  |
| Area  | Number and type of Means of Protection: MOOP, MOPP | CTI   | Working voltage  |                              | Required creepage (mm) | Required clearance (mm)             | Measured creepage (mm) | Measured clearance (mm) | Remarks                                  |
|   |  |   | V <sub>rms</sub> | V <sub>pk</sub>              |                        |                                     |                        |                         |  |
| A   | 1MOOP  | IIIb  | <300             | <420                         | 3.2 (acc. to Table 16) | 3.0 (2.0x1.48) (acc. to Table 8&13) | 3.8                    | 3.8                     | Primary traces before fuse               |
| A   | 1MOOP  | IIIb  | <300             | <420                         |                        |                                     | 3.3                    | 3.3                     | Primary traces under fuse F1A            |
| A   | 1MOOP  | IIIb  | <300             | <420                         |                        |                                     | 3.3                    | 3.3                     | Primary traces under fuse F1B (Optional) |

| IEC 60601-1  |                    |      |                                |                               |                                  |  |  |                                     |   |
|--|--------------------|------|--------------------------------|-------------------------------|----------------------------------|--|--|-------------------------------------|---|
| Clause   | Requirement + Test |      |                                |                               | Result - Remark                  |  |  |                                     | Verdict   |
| B  | 1MOPP              | IIIb | <250                           | <354                          | 4.0<br>(acc. to<br>Table 12)     | 3.3<br>(2.5x1.29)<br>(acc. to<br>Table 8&12) | 6.8                                    | 6.8                                 | N to PB (only<br>for earthed<br>construction)                                       |
| D  | 1MOPP              | IIIb | <250                           | <354                          |                                  |  | 5.4                                    | 5.4                                 | L to nearest<br>screw (metal<br>enclosure)<br>(Only for<br>earthed<br>construction) |
| D  | 1MOPP              | IIIb | <250                           | <354                          |                                  |  | 7.0                                    | 7.0                                 | Under C2 (only<br>for earthed<br>construction)                                      |
| B  | 1MOPP              | IIIb | <250                           | <354                          |                                  |  | 4.4                                    | 4.4                                 | Under C3 (only<br>for earthed<br>construction)                                      |
| B  | 1MOPP              | IIIb | <250                           | <354                          |                                  |  | 6.2                                    | 6.2                                 | Trace under<br>C5   |
| E  | 1MOPP              | IIIb | <250                           | <354                          |                                  |  | 6.0<br>(with slot<br>6.6mm x<br>1.1mm) | 3.6                                 | Under C52   |
| C  | 2MOPP              | IIIb | <250                           | <354                          | 8.0<br>(acc. to<br>Table 12)     | 6.5<br>(5.0x1.29)<br>(acc. to<br>Table 8&12) | 12.2                                   | 9.8                                 | Trace under<br>C5+C52   |
| C  | 2MOPP              | IIIb | <250                           | <354                          |                                  |  | 8.1                                    | 8.1                                 | Between<br>PC101/2/3/4/5  |
| C  | 2MOPP              | IIIb | <250                           | <354                          |                                  |  | 10.8                                   | 10.8                                | Pin 2 and Pin 8<br>of T2  |
| C  | 2MOPP              | IIIb | <250                           | <354                          |                                  |  | 8.6                                    | 8.6                                 | Between C6<br>and C51B with<br>2 N  |
| C  | 2MOPP              | IIIb | 271                            | 464                           | 12.0<br>(acc. to<br>Table 12)    | 9.1<br>(7.0x1.29)<br>(acc. to<br>Table 8&12) | >12.5                                  | 9.3                                 | Traces under<br>T1 with a slot<br>4.9mmx29mm  |
| C  | 2MOPP              | IIIb | 369                            | 580                           | 12.0<br>(acc. to<br>Table 12)    | 9.1<br>(7.0x1.29)<br>(acc. to<br>Table 8&12) | 12.7                                   | 11.1                                | Traces under<br>T2  |
| <b>Supplementary Information:</b>  |                    |      |                                |                               |                                  |  |  |                                     |   |
| 1. For clearance and creepage did not describe as above are far larger than limit. |                    |      |                                |                               |                                  |  |  |                                     |   |
| 2. For all models  |                    |      |                                |                               |                                  |  |  |                                     |   |
| TABLE: transformers  |                    |      |                                |                               |                                  |  |  |                                     | Pass  |
| Area   | Tested insulation  |      | Working<br>voltage<br>peak (V) | Working<br>voltage<br>rms (V) | Required<br>electric<br>strength | Required<br>clearance<br>dist. (mm)          | Required<br>creepage<br>dist. (mm)     | Required<br>distance<br>thr. insul. |   |

| IEC 60601-1                       |  |     |     |                            |                                     |                              |  |
|-----------------------------------|--|-----|-----|----------------------------|-------------------------------------|------------------------------|--|
| Clause                            | Requirement + Test   |     |     | Result - Remark            |                                     |                              | Verdict  |
| C                                 | T1 Primary to secondary (2MOPP)  | 464 | 271 | 4320 Vac (acc. to Table 6) | 9.1 (7.0x1.29) (acc. to Table 8&12) | 12.0 (acc. to Table 12)      | 0.4  |
| C                                 | T1 Primary to core (1MOPP)   | 464 | 271 | 1660 Vac (acc. to Table 6) | 4.6 (3.5x1.29) (acc. to Table 8&12) | 6.0 (acc. to Table 12)       | 0.4  |
| C                                 | T1 Secondary to core (1MOPP)   | 464 | 271 | 1660 Vac (acc. to Table 6) | 4.6 (3.5x1.29) (acc. to Table 8&12) | 6.0 (acc. to Table 12)       | 0.4  |
| C                                 | T2 Primary to secondary (2MOPP)  | 580 | 369 | 4641 Vac (acc. to Table 6) | 9.1 (7.0x1.29) (acc. to Table 8&12) | 12.0 (acc. to Table 12)      | 0.4  |
| C                                 | T2 Core to secondary (2MOPP)   | 580 | 369 | 4641 Vac (acc. to Table 6) | 9.1 (7.0x1.29) (acc. to Table 8&12) | 12.0 (acc. to Table 12)      | 0.4  |
| Loc.                              | Tested insulation  |     |     | Test voltage/ V            | Measured clearance dist. (mm)       | Measured creepage dist. (mm) | Measured distance thr. insul. (mm); number of layers |
| C                                 | T1 Primary to secondary (2MOPP):<br>- primary winding to secondary winding (ext.)<br>- primary winding to secondary winding (int.) |     |     | 4320 Vac                   | 19.9<br>--                          | 19.9<br>--                   | --<br>2.0  |
| C                                 | T1 Primary to core (1MOPP):<br>- primary winding to core (ext.)<br>- primary winding to core (int.)                                |     |     | 1660 Vac                   | 6.2<br>--                           | 6.2<br>--                    | --<br>0.8  |
| C                                 | T1 Secondary to core (1MOPP):<br>- secondary winding to core (ext.)<br>- secondary winding to core (int.)                          |     |     | 1660 Vac                   | 6.2<br>--                           | 6.2<br>--                    | --<br>0.8  |
| C                                 | T2 Primary to secondary (2MOPP):<br>- primary winding to secondary winding (ext.)<br>- primary winding to secondary winding (int.) |     |     | 4320 Vac                   | 12.5<br>TIW                         | 12.5<br>TIW                  | 9.5<br>--  |
| C                                 | T2 Core to secondary (2MOPP):<br>- primary core to secondary winding (ext.)<br>- primary core to secondary winding (int.)          |     |     | 4320 Vac                   | 9.3<br>TIW                          | 9.3<br>TIW                   | 3.1<br>--  |
| <b>Supplementary information:</b> |  |     |     |                            |                                     |                              |  |

| IEC 60601-1 |                    |                 |         |
|-------------|--------------------|-----------------|---------|
| Clause      | Requirement + Test | Result - Remark | Verdict |

|    |   |  |  |
|----|---|--|--|
| 1. | The core of T1 is considered as floating.                                       |  |  |
| 2. | The core of T2 is considered as primary parts.                                  |  |  |
| 3. | Triple insulated wire is used as secondary winding of T2.                       |  |  |
| 4. | For clearance and creepage did not describe as above are far larger than limit. |  |  |
| 5. | The transformer construction for all models of all sources is identical.        |  |  |

### **INSULATION DIAGRAM CONVENTIONS and GUIDANCE:**

A measured value must be provided in the value columns for the device under evaluation. The symbol > (greater than sign) must not be used. Switch-mode power supplies must be re-evaluated in the device under evaluation therefore N/A must not be used with a generic statement that the component is certified.

Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:

- All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.
- Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional
- Applied parts are extended beyond the equipment enclosure and terminated with an arrow.
- Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.