Test Report issued under the responsibility of:

TÜVRheinland®

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

| | |
|---|---|
| **Report Number. ..... :** | **CN22V2XI 001** |
| **Date of issue ..... :** | 2023-06-21 |
| **Total number of pages ..... :** | 229 (excluding report attachments, see page 3) |
| **Name of Testing Laboratory preparing the Report ..... :** | TÜV Rheinland Shanghai Co. Ltd. |
| **Applicant's name ..... :** | TDK-Lambda (China) Electronics Co., Ltd |
| **Address ..... :** | No. 95, Zhujiang Road, Xinwu District, Wuxi, 214028 Jiangsu, P.R. China |
| **Test specification:** | |
| **Standard ..... :** | IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020 |
| **Test procedure ..... :** | CB Scheme |
| **Non-standard test method ..... :** | N/A |
| **TRF template used ..... :** | IECEE OD-2020-F1:2020, Ed.1.3 |
| **Test Report Form No. ..... :** | IEC60601_1U |
| **Test Report Form(s) Originator.... :** | UL(US) |
| **Master TRF ..... :** | 2022-05-13 |



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 IECEE 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 NCB. 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 |
| **Trade Mark(s)..... :** | **TDK·Lambda** |
| **Manufacturer..... :** | Same as applicant |
| **Model/Type reference..... :** | CUS600M**y-zxxxxxxx**, CME600A**y-zxxxxxxx**<br>(**y** = blank; **z** = 12, 19, 24, 28, 32, 36 or 48; **xxxxxxx** =/ADJ, /T, /J, /M, /C or /CO, /C2 or /CO2, /SF, /G, /EF, /EFM, /GEK, other alphanumeric character, symbol or blank)<br>Refer to page 13 for definition of variables |
| **Ratings..... :** | AC input: 100-240V, 50-60Hz, 4.5A or 7.0A<br>DC output: See the model list on pages 8-10 for details |

**Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):**

| | | | |
|---|---|---|---|
| ☒ | **CB Testing Laboratory:** | TÜV Rheinland Shanghai Co. Ltd. | |
| **Testing location/ address.....:** | | No.177, 178, Lane 777 West Guangzhong Road, Jing'an District, Shanghai, China | |
| **Tested by (name, function, signature).....:** | | Hope Chen / Expert | Hope Chen |
| **Approved by (name, function, signature)...:** | | Jiali Ni / Reviewer | Jiali Ni |
| ☐ | **Testing procedure: CTF Stage 1:** | N/A | |
| **Testing location/ address.....:** | | | |
| **Tested by (name, function, signature).....:** | | | |
| **Approved by (name, function, signature)...:** | | | |
| ☐ | **Testing procedure: CTF Stage 2:** | N/A | |
| **Testing location/ address.....:** | | | |
| **Tested by (name, function, signature).....:** | | | |
| **Witnessed by (name, function, signature)..:** | | | |
| **Approved by (name, function, signature)...:** | | | |
| ☐ | **Testing procedure: CTF Stage 3:** | N/A | |
| ☐ | **Testing procedure: CTF Stage 4:** | N/A | |
| **Testing location/ address.....:** | | | |
| **Tested by (name, function, signature).....:** | | | |
| **Witnessed by (name, function, signature)..:** | | | |
| **Approved by (name, function, signature)...:** | | | |
| **Supervised by (name, function, signature) :** | | | |

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

- ATTACHMENT 1 – National Differences (19 pages)
- ATTACHMENT 2 – Photo Documentation (17 pages)

Note: Total number of pages in each attachment indicated in individual attachment.

**Summary of testing:**

| **Tests performed (name of test and test clause):** | **Testing location:** |
|---|---|
| This report is based on original CBTRs 50326710 001 to 003 issued by TÜV Rheinland with following changes:<br>- Update test standard to IEC 60601-1:2005/AMD2:2020<br>- Added additional construction for the product, see page 8 and attached photo documentation for more details.<br>No technical changes have been found by construction review at the provided sample and/or other administrative modifications.<br>Following additional tests and evaluations per the requirements of the new standard and/or considered necessary were conducted in this report:<br>- Check and update certificate validity of critical components.<br>Except stated above, all test data are derived from original CB test report.<br>The equipment has been evaluated for ambient temperature up to 70 °C.<br>Specified ambient temperature for operation is according to manufacturer's specification. (see chart of convection cooling and force air cooling on following)<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.<br>Unless otherwise specified, throughout this report, 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. | See page 2. |

**Summary of compliance with National Differences (List of countries addressed):**

US, CA.

Explanation of used codes: US=United States of America, CA=Canada.

☒ **The product fulfils the requirements of**

EN 60601-1:2006+A1:2013+A12:2014+A2:2021

ANSI/AAMI ES60601-1:2005+A2:2010(R2012)+A1:2012+A2:2021

CAN/CSA-C22.2 No. 60601-1:14+A2:22

**Statement concerning the uncertainty of the measurement systems used for the tests**

(may be required by the product standard or client)

☒ **Internal procedure used for type testing through which traceability of the measuring uncertainty has been established:**

**Procedure number, issue date and title:**

Evaluation of Measurement Uncertainty in Laboratory and Decision Rule (Ref. No. MS-0007539, issued date: Apr. 7, 2023).

Calculations leading to the reported values are on file with the NCB and testing laboratory that conducted the testing.

☐ **Statement not required by the standard used for type testing**

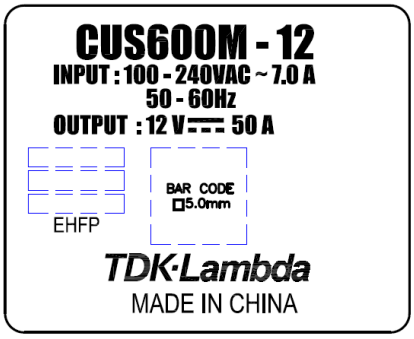
(Note: When IEC or ISO standard requires a statement concerning the uncertainty of the measurement systems used for tests, this should be reported above. The informative text in parenthesis should be delete in both cases after selecting the applicable option)

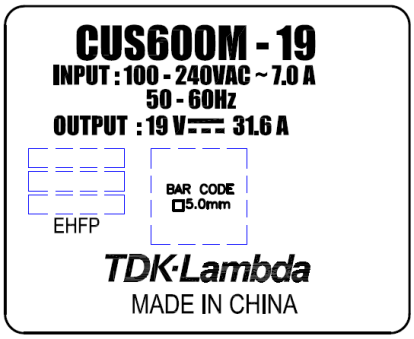
**Copy of marking plate:**

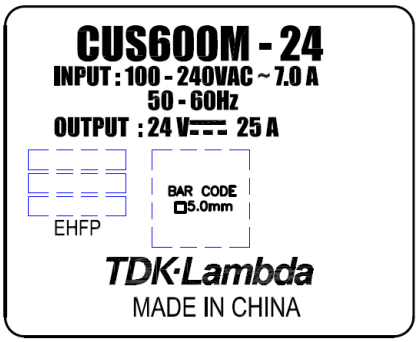
**The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.**

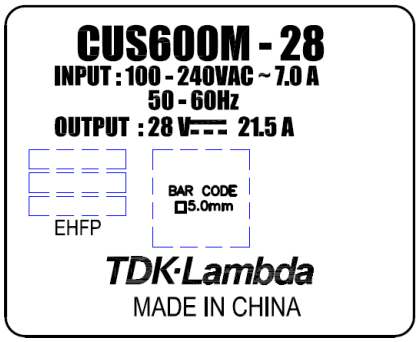
**<Representative>**

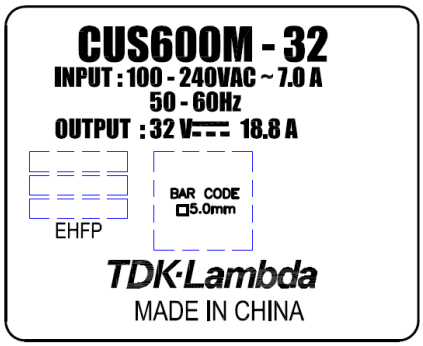
**Marking for CUS600M series**

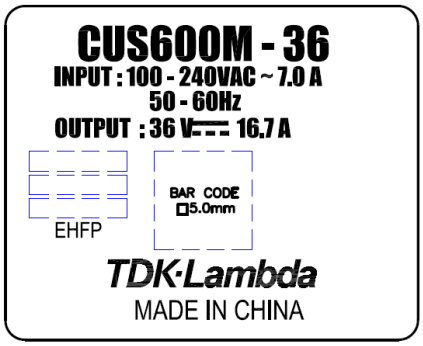


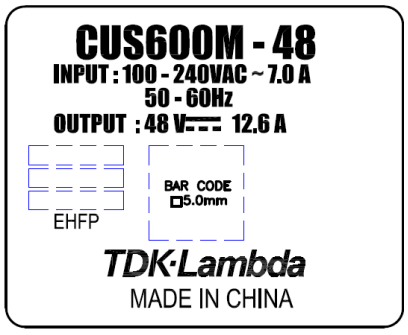



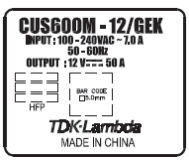



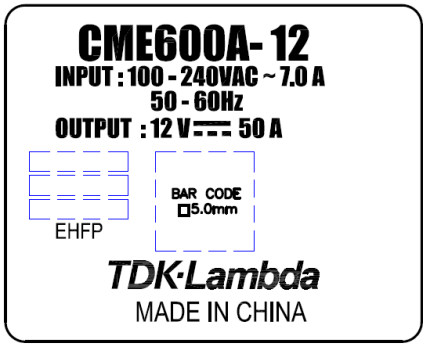



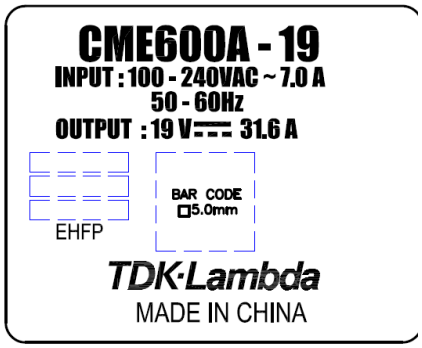



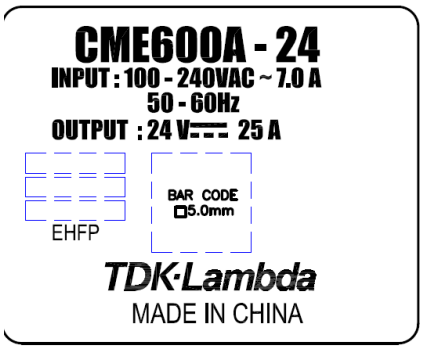



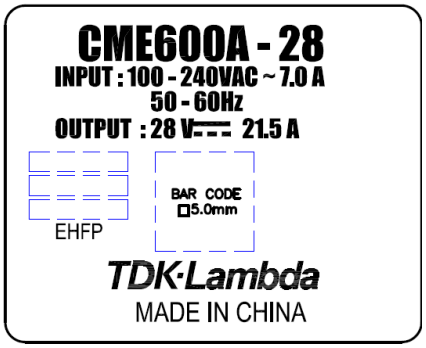



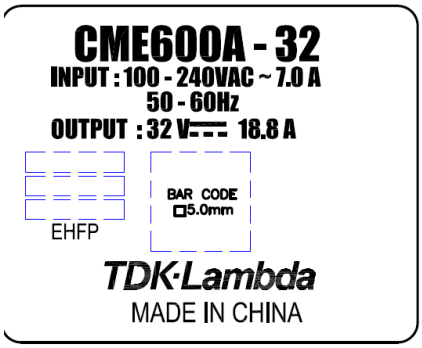
**Cont.** **Marking for CME600A series**

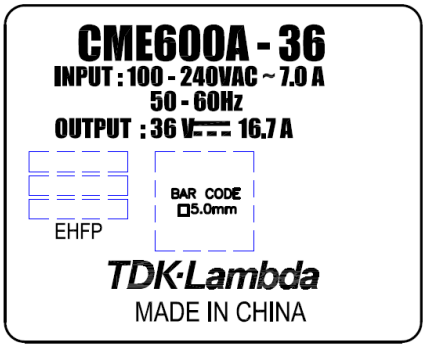


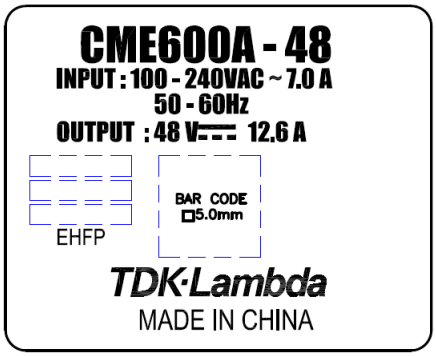




Remark: The rating labels of all models have the same design except for the model designation.

| | |
|---|---|
| **Test item particulars .....:** | For not classified ME equipment and a built-in, open frame type switching mode power supply |
| **Classification of installation and use.....:** | Fixed |
| **Supply Connection .....:** | Primary connector |
| **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 |
| **Accessories and detachable parts included……...:** | None |
| **Other options include……...:** | None |
| **Possible test case verdicts:** | |
| **- test case does not apply to the test object..... :** | N/A |
| **- test object does meet the requirement..... :** | P (Pass) |
| **- test object was not evaluated for the requirement……..:** | N/E (collateral standards only) |
| **- test object does not meet the requirement..... :** | F (Fail) |
| **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 |
| **Testing ..... :** | |
| **Date of receipt of test item..... :** | 2023-03-05 |
| **Date (s) of performance of tests ..... :** | 2023-03-06 (Construction Check) |
| | |
| **General remarks:** | |
| "(See Enclosure #)" refers to additional information appended to the report.<br>"(See appended table)" refers to a table appended to the report.<br><br>**Throughout this report a ☐ comma / ☒ point is used as the decimal separator.** | |
| **Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:** | |
| 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)..... :** | 1. TDK-Lambda (China) Electronics Co., Ltd.<br>No. 95, Zhujiang Road, Xinwu District, Wuxi<br>214028 Jiangsu P.R. China<br>2. TDK-Lambda Malaysia Sdn. Bhd.<br>PLO 33, Kawasan Perindustrian Senai<br>81400 Senai, Johor Malaysia<br>3. Zhangjiagang Hua Yang Electronics Co., Ltd.<br>Zhao Feng Industrial Zone, Leyu Town<br>Zhangjiagang, 215622 Jiangsu, P.R. China |

**General product information and other remarks:**

The PSU is a component type switching mode power supplies intended for the earthed construction or non-earthed construction of medical equipment.

- For earthed construction (Class I), the PSU need to be reliably earthed and professionally installed and fixed with metal screws.

- 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.

Model CME600A**y-zxxxxxxx** is identical to model CUS600M**y-zxxxxxxx** except for model name.

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.

The additional construction of model CUS600M/EFM is based on CUS600M/EF with following changes:

- Change point is only for standby circuit.
- Output voltage & power of standby is as same as CUS600M/EF.
- PCB changes are all in the secondary circuit of standby power. The distance between primary and secondary is no changed. The distance between the secondary and ground is no changed.

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

| Series Model | I/p voltage (Vac) | Freq (Hz) | I/p current (A) | Output Channel | Minimal output | Rated output (typical) | Maximum output |
|---|---|---|---|---|---|---|---|
| **Convection cooling condition** | | | | | | | |
| CUS600M**y-12xxxxxxx**<br>CME600A**y-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) | | |
| CUS600M-12/GEKxxxx | 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) | 5.25Vdc (Rated) | | |
| | | | | | 1.9A (Rated) | | |
| CUS600M**y-19xxxxxxx**<br>CME600A**y-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. | | |

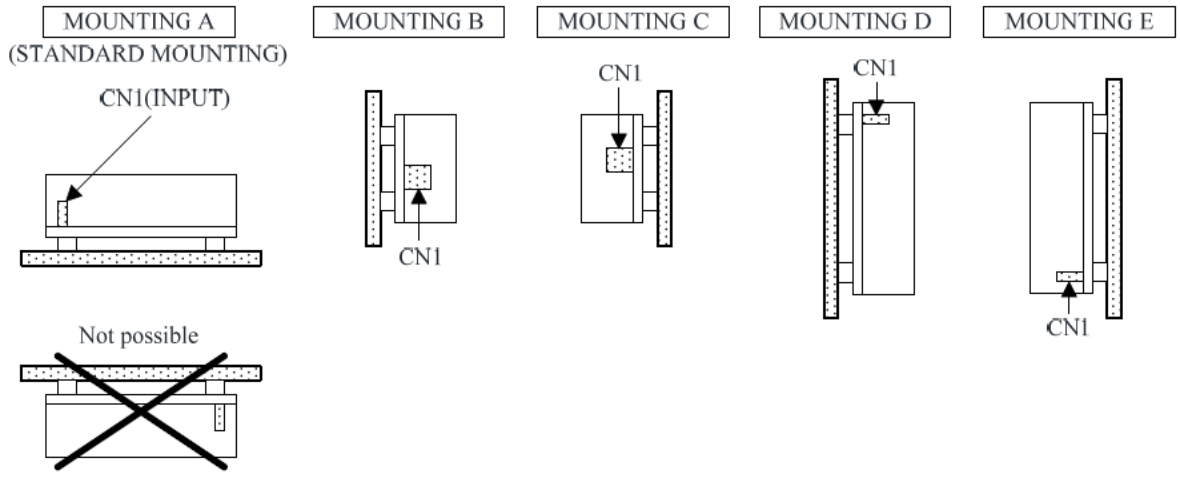
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | (Dynamic) | | |
| | | | | Standby power (Optional) | 5Vdc (Rated) | | |
| | | | | | 2A (Rated) | | |
| CUS600M**y**-24**xxxxxxx**<br>CME600A**y**-24**xxxxxxx** | 100-240 | 50-60 | 4.5 | Main output | 21.6Vdc | 24Vdc | 25.9Vdc |
| | | | | | 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) | | |
| CUS600M**y**-28**xxxxxxx**<br>CME600A**y**-28**xxxxxxx** | 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) | | |
| CUS600M**y**-32**xxxxxxx**<br>CME600A**y**-32**xxxxxxx** | 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.<br>(Dynamic) | | |
| | | | | Standby power (Optional) | 5Vdc (Rated) | | |
| | | | | | 2A (Rated) | | |
| CUS600M**y**-36**xxxxxxx**<br>CME600A**y**-36**xxxxxxx** | 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.<br>(Dynamic) | | |
| | | | | Standby power (Optional) | 5 Vdc (Rated) | | |
| | | | | | 2 A (Rated) | | |
| CUS600M**y**-48**xxxxxxx**<br>CME600A**y**-48**xxxxxxx** | 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.<br>(Dynamic) | | |
| | | | | Standby power (Optional) | 5 Vdc (Rated) | | |
| | | | | | 2A (Rated) | | |
| **Forced air cooling condition (airflow: air velocity 2.7m/s & air volume 28.6CFM)** | | | | | | | |
| CUS600M**y**-12**xxxxxxx**<br>CME600A**y**- | 100-240 | 50-60 | 7.0 | Main output | 10.8Vdc | 12Vdc | 12.9Vdc |
| | | | | | 50A | 50A | 46.6A |
| | | | | Standby | 5Vdc (Rated) | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 12**xxxxxxx** | | | | power (Optional) | 2A (Rated) | | |
| CUS600M-12/GEKxxxx | 100-240 | 50-60 | 7.0 | Main output | 10.8Vdc | 12Vdc | 12.9Vdc |
| | | | | | 50A | 50A | 46.6A |
| | | | | Standby power (Optional) | 5.25Vdc (Rated) | | |
| | | | | | 1.9A (Rated) | | |
| CUS600M**y**-19**xxxxxxx** CME600A**y**-19**xxxxxxx** | 100-240 | 50-60 | 7.0 | Main output | 17.1Vdc | 19Vdc | 20.5Vdc |
| | | | | | 31.6A | 31.6A | 29.3A |
| | | | | Standby power (Optional) | 5Vdc (Rated) | | |
| | | | | | 2A (Rated) | | |
| CUS600M**y**-24**xxxxxxx** CME600A**y**-24**xxxxxxx** | 100-240 | 50-60 | 7.0 | Main output | 21.6Vdc | 24Vdc | 25.9Vdc |
| | | | | | 25A | 25A | 23.2A |
| | | | | Standby power (Optional) | 5Vdc (Rated) | | |
| | | | | | 2A (Rated) | | |
| CUS600M**y**-28**xxxxxxx** CME600A**y**-28**xxxxxxx** | 100-240 | 50-60 | 7.0 | Main output | 25.2Vdc | 28Vdc | 30.2Vdc |
| | | | | | 21.5A | 21.5A | 20.0A |
| | | | | Standby power (Optional) | 5Vdc (Rated) | | |
| | | | | | 2A (Rated) | | |
| CUS600M**y**-32**xxxxxxx** CME600A**y**-32**xxxxxxx** | 100-240 | 50-60 | 7.0 | Main output | 28.8Vdc | 32Vdc | 34.5Vdc |
| | | | | | 18.8A | 18.8A | 17.5A |
| | | | | Standby power (Optional) | 5Vdc (Rated) | | |
| | | | | | 2A (Rated) | | |
| CUS600M**y**-36**xxxxxxx** CME600A**y**-36**xxxxxxx** | 100-240 | 50-60 | 7.0 | Main output | 32.4Vdc | 36Vdc | 38.8Vdc |
| | | | | | 16.7A | 16.7A | 15.5A |
| | | | | Standby power (Optional) | 5Vdc (Rated) | | |
| | | | | | 2A (Rated) | | |
| CUS600M**y**-48**xxxxxxx** CME600A**y**-48**xxxxxxx** | 100-240 | 50-60 | 7.0 | Main output | 43.2Vdc | 48Vdc | 51.8Vdc |
| | | | | | 12.6A | 12.6A | 11.7A |
| | | | | Standby power (Optional) | 5Vdc (Rated) | | |
| | | | | | 2A (Rated) | | |

Remark:

Operating temp.: up to +70ºC (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).

**MOUNTING DIRECTIONS**

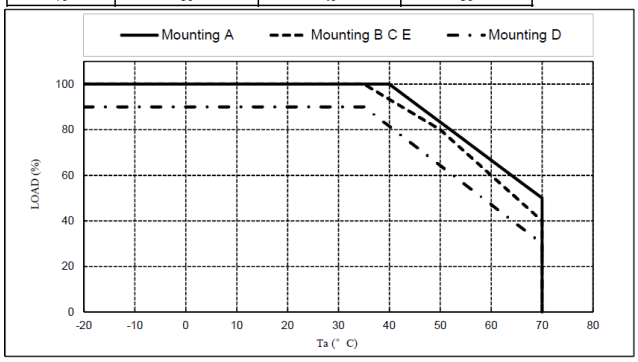



**Derating Curve:**

**Convection cooling condition**:

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

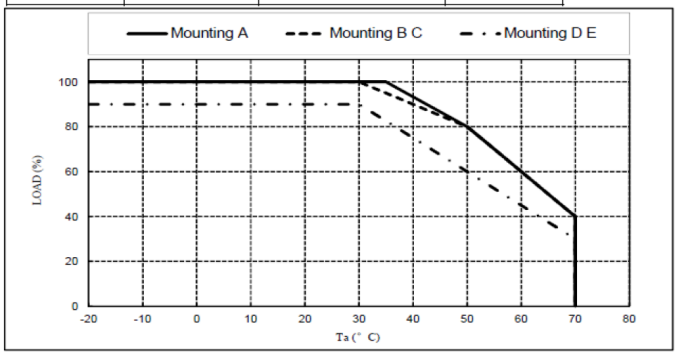
| Ta (°C) | Mounting A | Mounting B C E | Mounting D |
|---|---|---|---|
| | LOAD (%) | LOAD (%) | LOAD (%) |
| -20 - +35 | 100 | 100 | 90 |
| 40 | 100 | 93.3 | 81.4 |
| 50 | 83.3 | 80 | 64.3 |
| 60 | 66.7 | 60 | 47.1 |
| 70 | 50 | 40 | 30 |




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

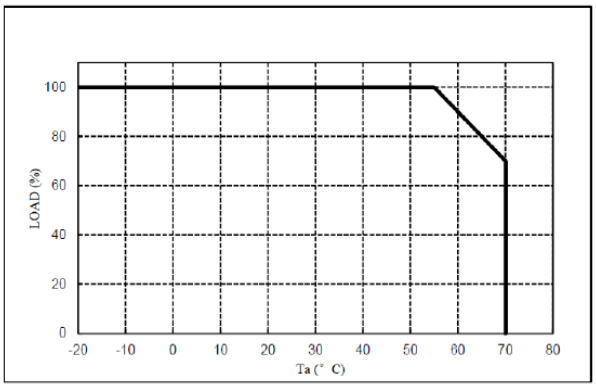
MODEL: ALL MODELS

| 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 |




**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 (℃)** |
|---|---|---|
| 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, C51D,C51E,C51F | Electrolytic Capacitors | 105 (12V,32V,36V,48V) 125 (19V,24V,28V) |
| C61 | Electrolytic Capacitor | 105 |

Note: PSU = Power Supply Unit

**Definition of variable(s):**

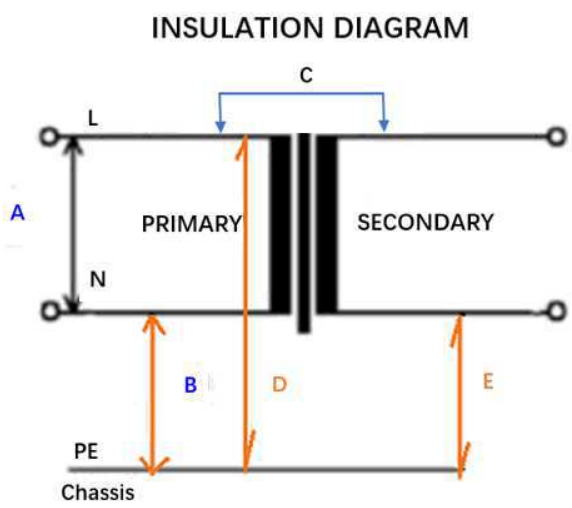
CUS600M**y-zxxxxxxx ,** CME600A**y-zxxxxxxx**

(**y** = blank; **z** = 12, 19, 24, 28, 32, 36 or 48; **xxxxxxx** =/ADJ, /T, /J, /M, /C or /CO, /C2 or /CO2, /SF, /G, /EF, /EFM, /GEK, other alphanumeric character, symbol or blank)

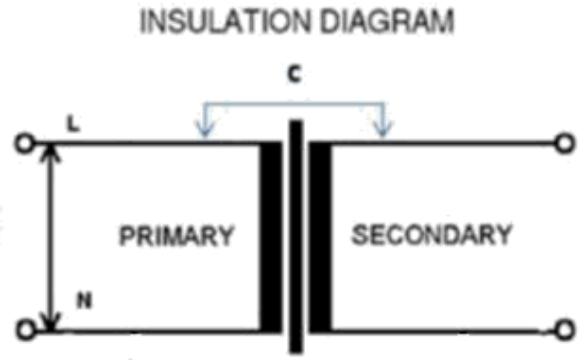
Note: Suffix options would be used shown below or used together.

| Variable: | Range of variable: | Content: |
|---|---|---|
| **y** | blank | - |
| **z** | 12, 19, 24, 28, 32, 36 or 48 | Denoting output voltage from 12 Vdc to 48 Vdc. |
| **xxxxxxx** | blank | Denoting for Standard model |
| | /ADJ | Denoting output adjustable |
| | /T | Denoting terminal block connector |
| | /J | Denoting JST connector |
| | /M | Denoting molex connector |
| | /C or /CO | Denoting single side PWB coating |
| | /C2 or /CO2 | Denoting double side PWB coating |
| | /SF | Denoting single fuse |
| | /G | Denoting low earth leakage current |
| | /EF | Denoting end fan. It is for class I construction only. |
| | /EFM | Denoting end fan with on/off control, it is for class I construction only. |
| | /GEK | Denoting standby power rated output voltage is 5.25Vdc |
| | other alphanumeric character, symbol | Used for market purposes, no construction differences and no safety impact. |

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




**Earthed Construction**




**Non-Earthed Construction**

| TABLE: INSULATION DIAGRAM | | Pass |
|---|---|---|
| Pollution degree ..... : | 2 | — |
| Overvoltage category ..... : | II | — |
| Altitude ..... : | 5000 | — |
| Additional details on parts considered as applied parts ..... : | ☒ None ☐ 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 |
|---|---|---|---|---|---|---|---|---|---|
| | | | $V_{rms}$ | $V_{pk}$ | | | | | |
| A | 1MOOP | IIIb | 240 | 340 | 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 | 240 | 340 | | | 3.5 | 3.5 | Primary traces under fuse F1A |
| A | 1MOOP | IIIb | 240 | 340 | | | 3.5 | 3.5 | Primary traces under fuse F1B (Optional) |

| IEC 60601-1 | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Clause | Requirement + Test | | | | | | Result - Remark | | Verdict |
| B | 1MOPP | IIIb | 240 | 340 | 4.0 (acc. to Table 12) | 3.3 (2.5x1.29) (acc. to Table 8&12) | 6.8 | 6.8 | N to PB (only for earthed construction) |
| D | 1MOPP | IIIb | 240 | 340 | | | 5.4 | 5.4 | L to nearest screw (metal enclosure) (Only for earthed construction) |
| D | 1MOPP | IIIb | 240 | 340 | | | 7.0 | 7.0 | Under C2 (only for earthed construction) |
| B | 1MOPP | IIIb | 240 | 340 | | | 4.4 | 4.4 | Under C3 (only for earthed construction) |
| B | 1MOPP | IIIb | 240 | 340 | | | 6.2 | 6.2 | Trace under C5 |
| E | 1MOPP | IIIb | 240 | 340 | | | 6.0 (with slot 6.6mm x 1.1mm) | 3.6 | Under C52 |
| C | 2MOPP | IIIb | 240 | 340 | 8.0 (acc. to Table 12) | 6.5 (5.0x1.29) (acc. to Table 8&12) | 12.2 | 9.8 | Trace under C5+C52 |
| C | 2MOPP | IIIb | 240 | 340 | | | 8.2 | 8.2 | Between PC101/2/3/4/5 |
| C | 2MOPP | IIIb | 240 | 340 | | | 10.8 | 10.8 | Pin 2 and Pin 8 of T2 |
| C | 2MOPP | IIIb | 240 | 340 | | | 8.6 | 8.6 | Between C6 and C51B with 2 N |
| C | 2MOPP | IIIb | 271 | 464 | 12.0 (acc. to Table 12) | 9.1 (7.0x1.29) (acc. to Table 8&12) | >12.5 | 9.3 | Traces under T1 with a slot 4.9mmx29mm |
| C | 2MOPP | IIIb | 369 | 580 | 12.0 (acc. to Table 12) | 9.1 (7.0x1.29) (acc. to Table 8&12) | 12.7 | 11.1 | Traces under T2 |

**Supplementary Information:**

For clearance and creepage did not describe as above are far larger than limit.

For all modules.

| TABLE: transformers | | | | | | | -- |
|---|---|---|---|---|---|---|---|
| Area | Tested insulation | Working voltage peak (V) | Working voltage rms (V) | Required electric strength | Required clearance dist. (mm) | Required creepage dist. (mm) | Required distance thr. insul. |
| C | T1 Primary to secondary (2MOPP) | 464 | 271 | 4320 Vac (acc. to Table 6) | 9.1 (7.0x1.29) (acc. to Table | 12.0 (acc. to Table 12) | 0.4 |

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

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | 8&12) | | |
| 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 |

| Area | 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.) | 4641 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.) | 4641 Vac | 9.3<br>TIW | 12.5<br>TIW | 3.1<br>-- |

**Supplementary information:**

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.

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

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.