Ref. Certif. No.

DE 2-044325

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

CB TEST CERTIFICATE

Product	Switching Power Supply
Name and address of the applicant	TDK-Lambda (China) Electronics Co., Ltd. No.95, Zhujiang Road, Xinwu District Wuxi, 214028 Jiangsu, P.R. China
Name and address of the manufacturer	TDK-Lambda (China) Electronics Co., Ltd. No.95, Zhujiang Road, Xinwu District Wuxi, 214028 Jiangsu, P.R. China
Name and address of the factory	See additional page(s)
Ratings and principal characteristics	Rated Input: 100-240Vac, 50-60Hz, 14A
Trademark (if any)	TDK-Lambda
Customer's Testing Facility (CTF) Stage used	N/A
Model / Type Ref.	CUS1200My-zxxxxxx, CME1200Ay-zxxxxxx, CUS1200-zxxxxxx, CWS1200-zxxxxxx (y=blank; z = 24, 36, 48; xxxxxxx =/CO, /CO2, /G, /SF, /CQC, other alphanumeric character, symbol or blank)
Additional information (if necessary may also be reported on page 2)	The risk management requirements of the standard were not addressed. The Usability evaluation has not been addressed. Rated Output: refer to the test report. For model differences, refer to the test report.
A sample of the product was tested and found to be in conformity with	IEC 60601-1:2005+A1+A2 See Test Report for National Differences
As shown in the Test Report Ref. No. which forms part of this Certificate	CN25D84W 001

This CB Test Certificate is issued by the National Certification Body

TÜVRheinland®

TÜV Rheinland LGA Products GmbH
Tillystr. 2, 90431 Nürnberg, Germany
Phone + 49 221 806-1371
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Mail: cert-validity@de.tuv.com
Web : www.tuv.com

Date: 2025-04-15

Signature: XiaoJun Ding

10/0861 CB 06/20v9 rk

1. TDK-Lambda (China) Electronics
   Co., Ltd.
   No.95, Zhujiang Road, Xinwu District
   Wuxi
   214028 Jiangsu, P.R. China

2. TDK-Lambda Malaysia Sdn. Bhd.
   PLO 33, Kawasan Perindustrian Senai
   81400 Senai, Johor
   Malaysia

Additional information (if necessary) Report Ref. No. : CN25D84W 001

Date: 2025-04-15 Signature: XiaoJun Ding

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..... :	CN25D84W 001
Date of issue ..... :	2025-04-15
Total number of pages ..... :	171 (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-F1:2023, Ed.1.6
Test Report Form No. ..... :	IEC60601_1K_PS
Test Report Form(s) Originator.... :	UL Solutions (US)
Master TRF ..... :	Dated 2024-04-12

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
Trademark(s) ..... :	TDK·Lambda
Manufacturer ..... :	Same as applicant
Model/Type reference ..... :	CUS1200My-zxxxxxx, CME1200Ay-zxxxxxx, CUS1200-zxxxxxx, CWS1200-zxxxxxx (y=blank; z = 24, 36, 48; xxxxxxx =/CO, /CO2, /G, /SF，/CQC, other alphanumeric character, symbol or blank)
Ratings ..... :	See the model list on page 8-9 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).....:		Kevin Liu / PE	
Approved by (name, function, signature)...:		Jiali Ni / Report Authorizer	
☐	**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 + 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 – National Differences (30 pages)
- ATTACHMENT – Photo Documentation (9 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:**
Clause 4.11 – Power input; Clause 5.7 – Humidity Preconditioning treatment; Clause 7.1.2 – Legibility of Marking; Clause 7.1.3 – Durability of Marking test; Clause 8.4.2 – Working voltage; Clause 8.4.3 – Plug discharge test; Clause 8.5.4 – Working voltage measurement; Clause 8.6.4 – Impedance and current-carrying capability of protective earth connections; Clause 8.7 – Leakage current test; Clause 8.8.3 – Dielectric strength test; Clause 8.8.4.1 – Ball pressure test of thermoplastic parts; Clause 11.1 – Maximum temperature during normal use; Clause 13.2 – Single fault conditions; Clause 15.5.1.2 – Transformer short circuit test Clause 15.5.1.3 – Transformer overload test Clause 15.5.2 - Transformer dielectric strength	TÜV Rheinland (Shanghai) Co., Ltd. No.177, 178, Lane 777 West Guangzhong Road, Jing'an District, Shanghai, China

Summary of compliance with National Differences

- IECEE Member countries that are also CENELEC members
  Compliance with Group Differences evaluated ☐ **yes** ☐ **No** ☒ N/A

- IECEE Member countries with published National Differences which were evaluated:
  US, CA, JP
  US= United States, CA= Canada, JP= Japan

- IECEE Member countries that did not publish any National Differences:
  N/A

To support compliance with published National Differences, attach a compilation of relevant ND and/or GD TRFs to the CB Test Report

☒ **The product fulfils the requirements of**

IEC 60601-1:2005+A1:2012+A2:2020

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

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

JIS T 0601-1:2023

Use of uncertainty of measurement for decisions on conformity (decision rule) :

☐ No decision rule is specified by the IEC standard, when comparing the measurement result with the applicable limit according to the specification in that standard. The decisions on conformity are made without applying the measurement uncertainty ("simple acceptance" decision rule, previously known as "accuracy method").

☒ Other:

Evaluation of Measurement Uncertainty in Laboratory and Decision Rule (Ref. No. MS-0007539, issued date: Jul. 28, 2023).

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

Information on uncertainty of measurement:

The uncertainties of measurement are calculated by the laboratory based on application of criteria given by OD-5014 for test equipment and application of test methods, decision sheets and operational procedures of IECEE.

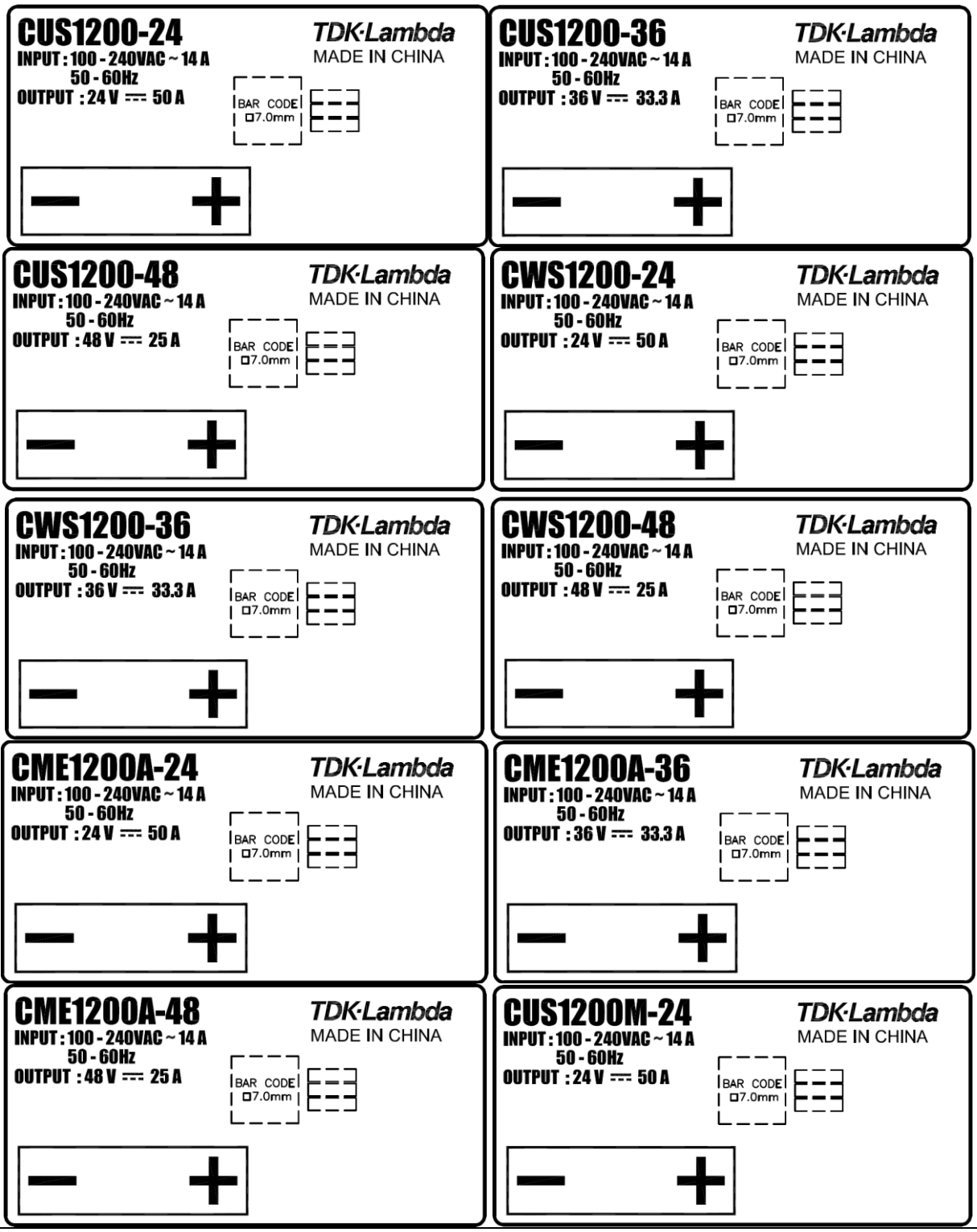
IEC Guide 115 provides guidance on the application of measurement uncertainty principles and applying the decision rule when reporting test results within IECEE scheme, noting that the reporting of the measurement uncertainty for measurements is not necessary unless required by the test standard or customer.

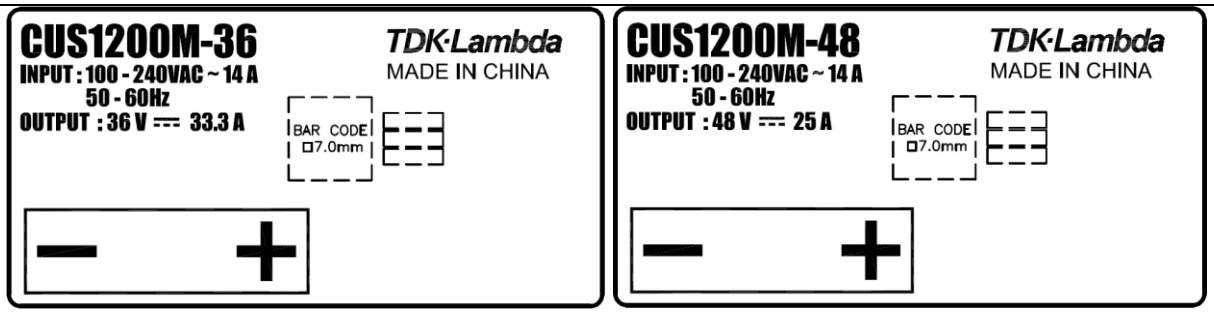
Calculations leading to the reported values are on file with the NCB and testing laboratory that conducted the testing.

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>





Note:

1. The marking plates for other models are of the same pattern except for model name.

Test item particulars.....:	
Classification of installation and use.....:	Fixed
Device Type .....:	Component power supply
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
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 .....:	2025-2-10
Date (s) of performance of tests.....:	2025-2-10 to 2025-03-21

General remarks:

"(See Enclosure #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

This Test Report Form is intended for the investigations of power supplies in accordance with IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020.

The Risk Management requirements were not addressed.

The Useability evaluation was not addressed

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** ☐ **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. No. 95, Zhujiang Road, Xinwu District, Wuxi 214028 Jiangsu, P.R. China

2. TDK-Lambda Malaysia Sdn. Bhd PLO33, Kawasan Perindustrian Senai, 81400 Senai Johor Malaysia

General product information and other remarks:

The PSU is a component type switching mode power supplies intended for use with the earthed construction medical equipment.

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

Model Differences:

Model CME1200Ay-zxxxxxxx & CUS1200-zxxxxxxx & CWS1200-zxxxxxxx are identical to model CUS1200My-zxxxxxxx except for model name.

Models with different outputs are identical, except for the turns of transformer and the different output ratings. The appearance of cooling fins for 48V is different to 24V or 36V.

See Model List below for details.

Full tests were performed on model CUS1200M-24, CUS1200M-36 & CUS1200M-48.

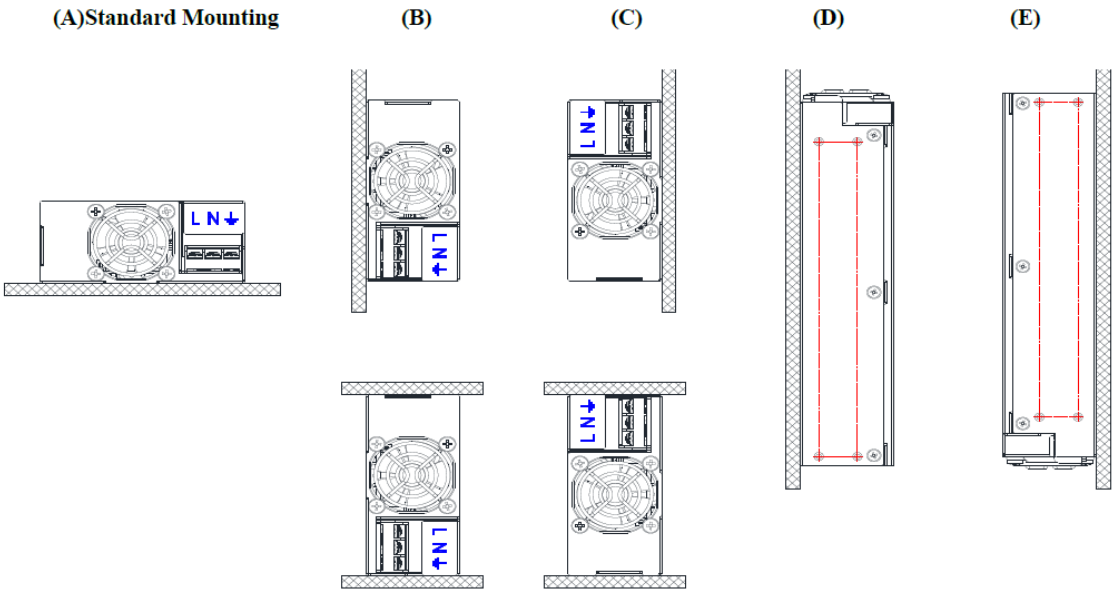
For rating differences between the models see below tables:

Table A for rating differences between the models:

Series Model	I/p voltage (Vac)	Freq (Hz)	I/p current (A)	Output Channel	Minimal output	Rated output (typical)	Maximum output
Forced air by build-in intake fan							
CUS1200My-**24xxxxxxx** CME1200Ay-**24xxxxxxx** CUS1200-**24xxxxxxx** CWS1200-**24xxxxxxx**	100-240	50-60	14	Main output	22.8 Vdc	24 Vdc	25.2 Vdc
					22.8Vdc~25.2Vdc, Normal: 50A & 1200W max.		
				Standby power (Optional)	4.8Vdc	5Vdc	5.2Vdc
					2A	2A	1.9A
CUS1200My-**36xxxxxxx** CME1200Ay-**36xxxxxxx** CUS1200-**36xxxxxxx** CWS1200-**36xxxxxxx**	100-240	50-60	14	Main output	34.2Vdc	36 Vdc	37.8 Vdc
					34.2Vdc~37.8Vdc, Normal: 33.3A & 1198.8W max.		
				Standby power (Optional)	4.8Vdc	5Vdc	5.2Vdc
					2A	2A	1.9A
CUS1200My-**48xxxxxxx**	100-240	50-60	14	Main output	45.6 Vdc	48 Vdc	50.4 Vdc
					45.6Vdc~50.4Vdc,		

CME1200Ay-**48xxxxxxx** CUS1200-**48xxxxxxx** CWS1200-**48xxxxxxx**					Normal: 25A & 1200W max.		
				Standby power (Optional)	4.8Vdc	5Vdc	5.2Vdc
					2A	2A	1.9A
Remark: Operating temp.: up to +70ºC (operating temperature depending on equipment's load, mounting position, for details refer to instruction manual).							

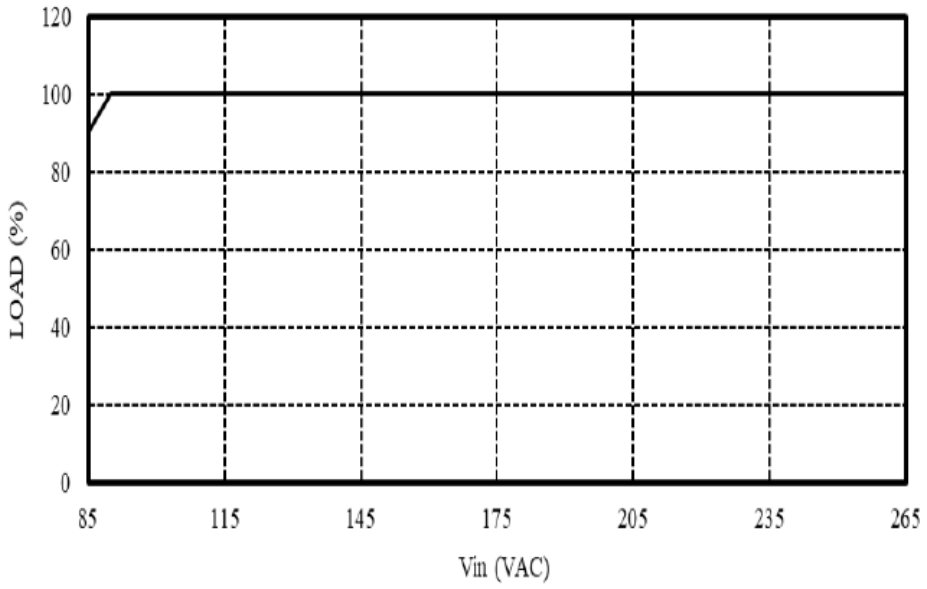
Mounting Directions:



Derating Curve:

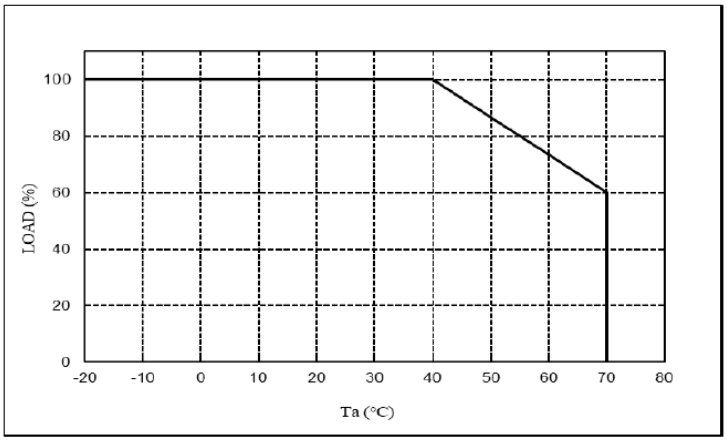
OUTPUT DERATING VERSUS INPUT VOLTAGE:

INPUT VOLTAGE (VAC)	MOUNTING A,B,C,D,E
	LOAD (%)
85	90
90~265	100



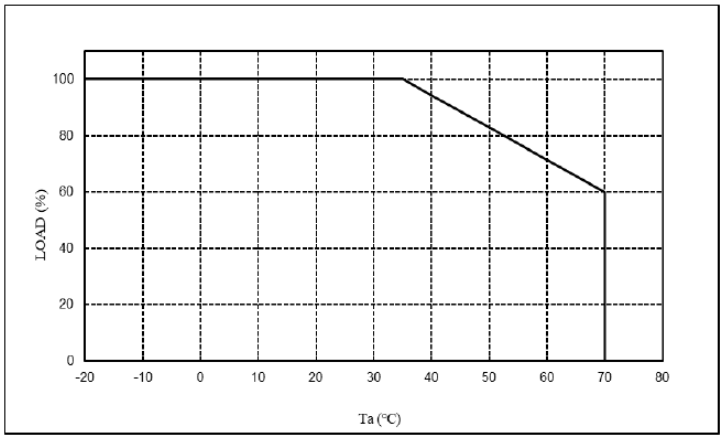
OUTPUT DERATING VERSUS OPERATING AMBIENT TEMPERATURE (Ta):

For model CUS1200M-36 & CUS1200M-48



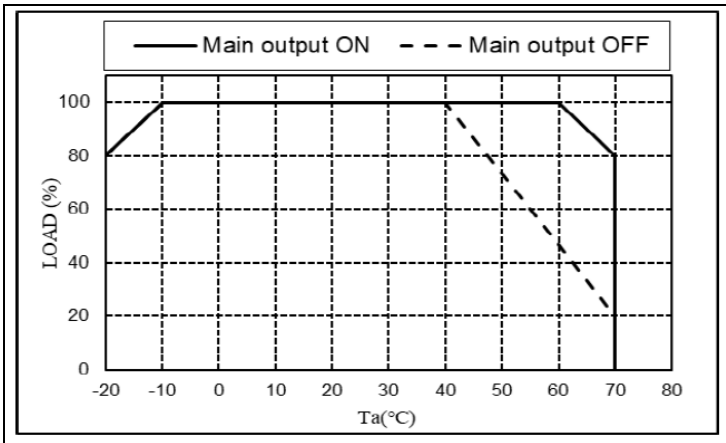
Ta (°C)	LOAD (%)
-20 - +40	100
50	86.7
60	73.3
70	60

For CUS1200M-24:



Ta (°C)	LOAD (%)
-20 - +35	100
40	94.3
50	82.9
60	71.5
70	60

STANDBY SUPPLY OUTPUT DERATING VERSUS OPERATING AMBIENT TEMPERATURE (TA):



Ta (°C)	LOAD (%)	
	Main output ON	Main output OFF
-20	80	80
-10 ~ 40	100	100
50	100	73.3
60	100	46.7
70	80	20

Definition of various:

CUS1200My-zxxxxxxx, CME1200Ay-zxxxxxxx, CUS1200-zxxxxxxx, CWS1200-zxxxxxxx

(y=blank; z = 24, 36, 48; xxxxxxx =/CO, /CO2, /G, /SF，/CQC, other alphanumeric character, symbol or blank)

(where “xxxxxxx” can be any alphanumeric character, symbol or blank, non safety relevant information.)

Variable:	Range of variable:	Content:
y	blank	Denotes for standard model
z	24, 36 or 48	Denoting output voltage 24Vdc, 36Vdc or 48Vdc.
xxxxxxx	blank	Denotes for standard model
	/CO	Denotes for single side PWB Coating
	/CO2	Denotes for double side PWB Coating
	/SF	Denotes for single fuse
	/G	Denotes for low earth Leakage current
	/CQC	Denotes for CQC approval
	other alphanumeric character, symbol	For market purposes, no construction differences and no safety impact.

Note: These suffixes may be used together (e.g. /G, /GCO)

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 a component type switching power supply, the overall compliance shall be investigated in the complete end system/equipment, in particular as:
  - 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. Overall consideration needed to re-check 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.

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

INSULATION DIAGRAM

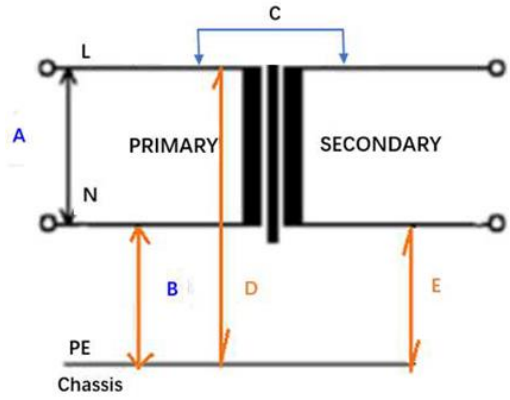


TABLE: INSULATION DIAGRAM		P
Pollution degree ..... :	2	—
Overvoltage category ..... :	II	—
Altitude ..... :	5000	—
Additional details on parts considered as applied parts ..... :	☒ None ☐ Areas _____ (See Clause 4.6 for details)	—

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	3.0	3.0 (2.0x1.48) (acc. to Table 8&13)	3.1	3.1	L to N before Fuse
A	1MOOP	IIIb	240	340			3.1	3.1	Trace under Fuse
B& D	1MOPP	IIIb	240	340	4.0 (acc. to Table 12)	3.3 (2.5x1.29) (acc. to Table 8&12)	4.7	4.7	Trace for Pri. to earth
B& D	1MOPP	IIIb	244	377			4.7	4.7	Trace under C2
B& D	1MOPP	IIIb	244	360			8.0	8.0	Trace under C4
B& D	1MOPP	IIIb	244	374			8.1	8.1	Trace under C5
B& D	1MOPP	IIIb	174	374			6.7	6.7	Trace under C6
C	2MOPP	IIIb	240	340	8.0 (acc. to Table 12)	6.5 (5.0x1.29) (acc. to Table 8&12)	8.2	8.2	Primary component / trace to secondary component / trace
C	2MOPP	IIIb	240	340			8.5	8.5	Trace under PC101,

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

									PC103, PC104, PC105 & PC106
C	2MOPP	IIIb	280	494	9.1	9.1 (7.0x1.29) (acc. to Table 8&12)	More than 11.9 3)	More than 11.9 3)	Trace Under Transformer T1
C	2MOPP	IIIb	280	494	9.1	9.1 (7.0x1.29) (acc. to Table 8&12)	More than 11.9 3)	More than 11.9 3)	- Pri. to Sec. (Int.)
C	1MOPP	IIIb	280	494	4.6	4.6 (3.5x1.29) (acc. to Table 8&12)	More than 6.0 3)	More than 6.0 3)	Transformer T1 Pri. to core
	1MOPP	IIIb	280	494	4.6	4.6 (3.5x1.29) (acc. to Table 8&12)	More than 6.0 3)	More than 6.0 3)	Transformer T1 Sec. to core
C	2MOPP	IIIb	197	464	7.2	6.5 (5.0x1.29) (acc. to Table 8&12)	8.2	8.2	Trace under Transformer T2 Pin 8 to Pin 2
C	2MOPP	IIIb	367	592	11.2	9.1 (7.0x1.29) (acc. to Table 8&12)	11.9	10.8	Trace under Transformer T2 (except Pin 8 to Pin 2)
C	2MOPP	IIIb	367	592	11.2	9.1 (7.0x1.29) (acc. to Table 8&12)	More than 14.6 3)	More than 14.6 3)	- Pri. to Sec. (Int.)
E	1MOPP	IIIb	240	340	4.0	3.3 (2.5x1.29) (acc. to Table 8&12)	4.2	4.2	Trace for Sec. to earth

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

Supplementary Information:

1). Core of Transformer T1 is considered as floating part, Core of Transformer T2 is considered of Pri. part.

2). Parts not listed in the table is much larger than the required value.

3). The values given by more than [minimum required value +30%] are acceptable according to OD-2020:2023 (sub-clause 5.6.1)

INSULATION DIAGRAM CONVENTIONS and GUIDANCE:

A measured value must be provided in the value columns for the device under evaluation. In case the measured minimum or maximum value is exceeding or is below the limit value by more than 30%, the value given in the TRF shall be >[minimum required value + 30%] or shall be < [maximum required value - 30%] and the accuracy of the used instruments shall be in line with the latest version of OD-5014, CTL Instrument Accuracy Limits (the latest version). 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 b4.10eyond 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.