Ref. Certif. No.

DE 2-040461-M1

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: 100-240 Vac, 50-60 Hz, for CUS800My-zxxxxxxx, CME800Ay-zxxxxxxx: 8.0 A or 9.5 A for CUS1000My-zxxxxxxx, CME1000Ay-zxxxxxxx: 9.5 A or 11.8 A
Trademark (if any)	TDK-Lambda
Customer's Testing Facility (CTF) Stage used	N/A
Model / Type Ref.	CUS800My-zxxxxxxx, CME800Ay-zxxxxxxx, CUS1000My-zxxxxxxx, CME1000Ay-zxxxxxxx (y = blank; z = 12,24,36,48; 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. For model differences, refer to the test report. Re-issue of DE 2-040461 dated 2023-11-15, due to first modification.
A sample of the product was tested and found to be in conformity with	IEC 60601-1:2005+A1+A2
As shown in the Test Report Ref. No. which forms part of this Certificate	CN23WOWH 002

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
Fax + 49 221 806-3935
Mail: cert-validity@de.tuv.com
Web : www.tuv.com

Date: 2024-09-26

Signature: XiaoJun Ding

10/0061 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. : CN23WOWH 002

Date: 2024-09-26 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. ..... :	CN23WOWH 002
Date of issue ..... :	2024-09-25
Total number of pages ..... :	37
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, 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 ..... :	2023-08-24

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 ..... :	CUS800My-zxxxxxxx, CME800Ay-zxxxxxxx, CUS1000My-zxxxxxxx, CME1000Ay-zxxxxxxx (y = blank; z = 12,24,36,48; xxxxxxx = /CO, /CO2, /G, /SF, /CQC other alphanumeric character, symbol or blank)
Ratings ..... :	See the model list on page 7 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 c/o TUV Rheinland Suzhou Co. Ltd. Pingqian (Taicang) Modern Industrial Park, No.525, Yuewang Lingang South Road, Shaxi Town, Taicang City, Jiangsu Province, China	
Tested by (name, function, signature).....:		Kevin Liu / Project Engineer	
Approved by (name, function, signature)...:		Jiali Ni / Reviewer	
☐	**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 – Photo Documentation (1 page)

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:**
Modification test report: CN23WOWH 002 This report is based on original CBTR CN23WOWH 001 with changes mentioned on page 7.	TUV Rheinland Suzhou Co. Ltd. Pingqian (Taicang) Modern Industrial Park, No.525, Yuewang Lingang South Road, Shaxi Town, Taicang City, Jiangsu Province, China

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**

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

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: Jul. 28, 2023).

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

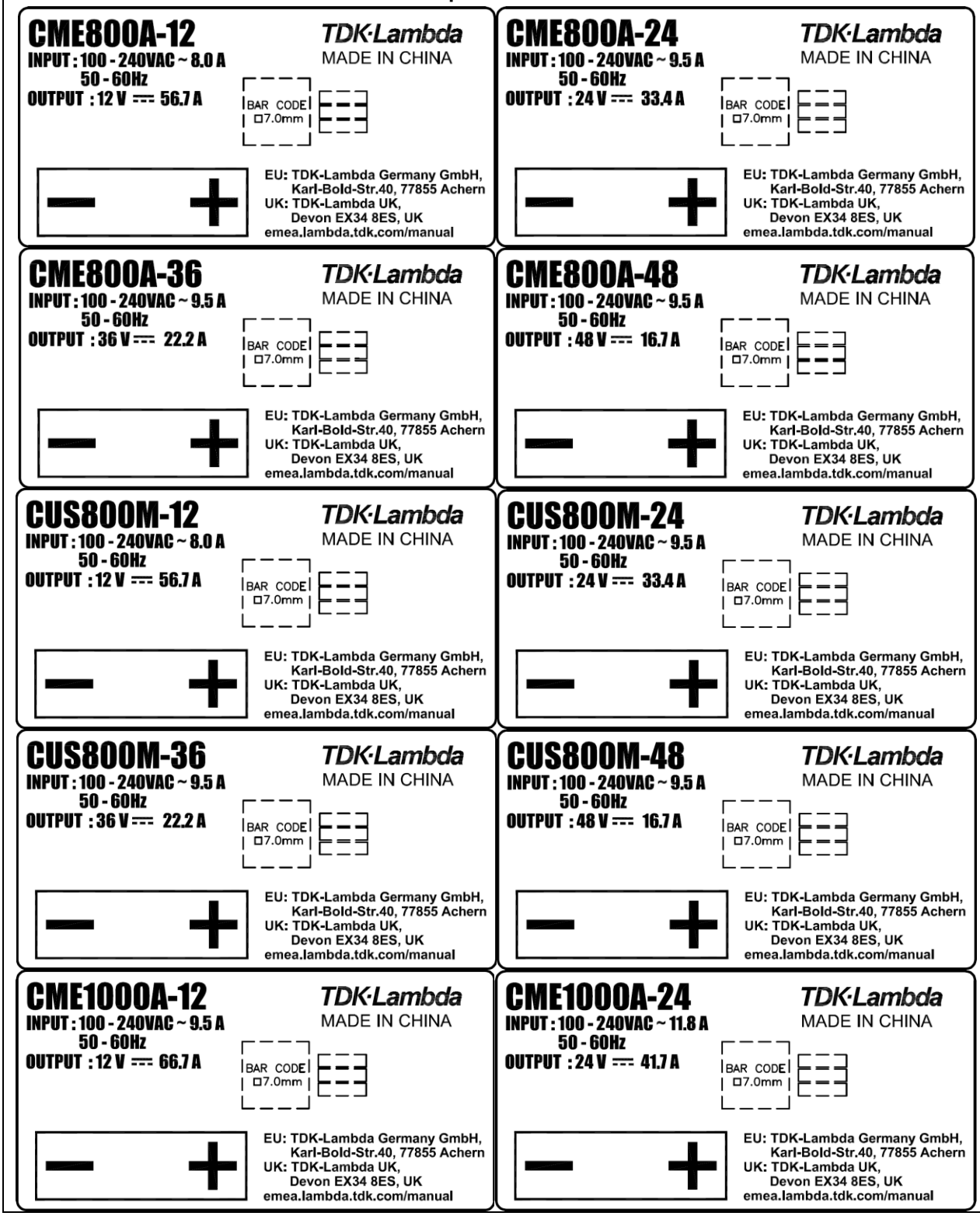
☐ **Statement not required by the standard used for type testing**

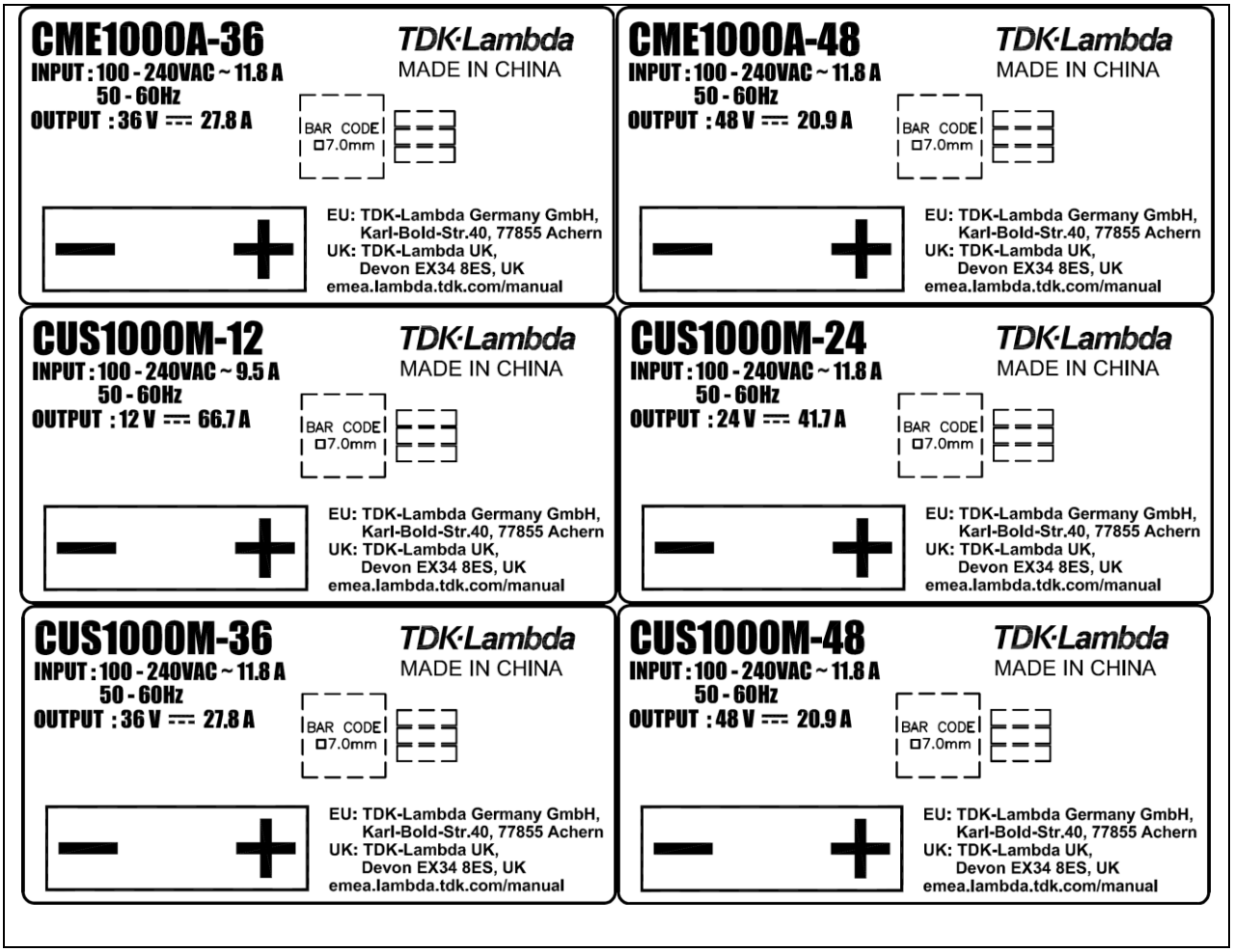
(Note: When IEC or ISO standard requires a statement concerning the uncertainty of the measurement systems used for tests, this should be reported above. The informative text in parenthesis should be delete in both cases after selecting the applicable option)

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 >




CME1000A-36
INPUT : 100 - 240VAC ~ 11.8 A
50 - 60Hz
OUTPUT : 36 V ⎓ 27.8 A
TDK·Lambda
MADE IN CHINA
BAR CODE
□7.0mm
EU: TDK-Lambda Germany GmbH,
Karl-Bold-Str.40, 77855 Achern
UK: TDK-Lambda UK,
Devon EX34 8ES, UK
emea.lambda.tdk.com/manual
CME1000A-48
INPUT : 100 - 240VAC ~ 11.8 A
50 - 60Hz
OUTPUT : 48 V ⎓ 20.9 A
TDK·Lambda
MADE IN CHINA
BAR CODE
□7.0mm
EU: TDK-Lambda Germany GmbH,
Karl-Bold-Str.40, 77855 Achern
UK: TDK-Lambda UK,
Devon EX34 8ES, UK
emea.lambda.tdk.com/manual
CUS1000M-12
INPUT : 100 - 240VAC ~ 9.5 A
50 - 60Hz
OUTPUT : 12 V ⎓ 66.7 A
TDK·Lambda
MADE IN CHINA
BAR CODE
□7.0mm
EU: TDK-Lambda Germany GmbH,
Karl-Bold-Str.40, 77855 Achern
UK: TDK-Lambda UK,
Devon EX34 8ES, UK
emea.lambda.tdk.com/manual
CUS1000M-24
INPUT : 100 - 240VAC ~ 11.8 A
50 - 60Hz
OUTPUT : 24 V ⎓ 41.7 A
TDK·Lambda
MADE IN CHINA
BAR CODE
□7.0mm
EU: TDK-Lambda Germany GmbH,
Karl-Bold-Str.40, 77855 Achern
UK: TDK-Lambda UK,
Devon EX34 8ES, UK
emea.lambda.tdk.com/manual
CUS1000M-36
INPUT : 100 - 240VAC ~ 11.8 A
50 - 60Hz
OUTPUT : 36 V ⎓ 27.8 A
TDK·Lambda
MADE IN CHINA
BAR CODE
□7.0mm
EU: TDK-Lambda Germany GmbH,
Karl-Bold-Str.40, 77855 Achern
UK: TDK-Lambda UK,
Devon EX34 8ES, UK
emea.lambda.tdk.com/manual
CUS1000M-48
INPUT : 100 - 240VAC ~ 11.8 A
50 - 60Hz
OUTPUT : 48 V ⎓ 20.9 A
TDK·Lambda
MADE IN CHINA
BAR CODE
□7.0mm
EU: TDK-Lambda Germany GmbH,
Karl-Bold-Str.40, 77855 Achern
UK: TDK-Lambda UK,
Devon EX34 8ES, UK
emea.lambda.tdk.com/manual

Test item particulars.....:	For class I ME equipment and a built-in 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 .....:	--
Date (s) of performance of tests.....:	--

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.

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. PLO 33, Kawasan Perindustrian Senai 81400 Senai, Johor Malaysia

General product information and other remarks:

This test report is valid only in conjunction with TÜV Rheinland test report No. CN23WOWH 001.

Test Report History: This report may consist of more than one report and is valid only with additional or previous issued reports.		
Ref. No.	Issued Date	Item
CN23WOWH 001	2023-11-06	Original test report

Description of change(s):

Previous approved models were modified as following:

1. Correct the typo error from ‘B825’ to ‘T825’ for Primary Terminal Block (TB1) in the List of critical components. See Table 8.10 in bold for details.
2. Add a new model ‘T302 series’ for Primary Terminal Block (TB1), which is identical to the previous model expect the appearance. Details refer to Table 8.10 & photo documentation.
3. Add the max. temperature for Insulation Sheet. See Table 8.10 in bold for details.

For the above described change, no test was considered necessary to be performed.

Only relevant clauses and tables were recorded in this report.

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
Forced air by build-in intake fan							
CUS800M-12xxxxxxx CME800A-12xxxxxxx	100-240	50-60	8.0	Main output	10.8Vdc	12Vdc	12.6 Vdc
					10.8Vdc~12.6Vdc, Normal: 56.7A & 680.4W max. Peak: 66.7A & 800.4W max. (Dynamic)		
				Standby mode power (optional)	4.8Vdc	5Vdc	5.2Vdc
					2A	2A	1.9A
CUS800M-24xxxxxxx CME800A-24xxxxxxx	100-240	50-60	9.5	Main output	21.6 Vdc	24Vdc	25.9 Vdc
					21.6Vdc~25.9Vdc, Normal: 33.4A & 801.6W max.		
				Standby mode power (optional)	4.8Vdc	5Vdc	5.2Vdc
					2A	2A	1.9A
CUS800M-36xxxxxxx CME800A-36xxxxxxx	100-240	50-60	9.5	Main output	32.4 Vdc	36 Vdc	38.8Vdc
					32.4Vdc~38.8Vdc, Normal: 22.2A & 799.2W max.		
				Standby mode power (optional)	4.8Vdc	5Vdc	5.2Vdc
					2A	2A	1.9A
CUS800M-48xxxxxxx CME800A-48xxxxxxx	100-240	50-60	9.5	Main output	43.2Vdc	48 Vdc	51.8Vdc
					43.2Vdc~51.8Vdc, Normal: 16.7A & 801.6W max.		
				Standby mode power (optional)	4.8Vdc	5Vdc	5.2Vdc
					2A	2A	1.9A
Remark 1: Operating temp.: up to +70ºC (operating temperature depending on equipment's load, mounting position, for details refer to instruction manual).							
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							
CUS1000M-12xxxxxxx CME1000A-12xxxxxxx	100-240	50-60	9.5	Main output	10.8Vdc	12Vdc	12.6 Vdc
					10.8Vdc~12.6Vdc, Normal: 66.7A & 800.4W max. Peak: 83.4A & 1000.8W max. (Dynamic)		

				Standby mode power (optional)	4.8Vdc	5Vdc	5.2Vdc
					2A	2A	1.9A
CUS1000M-24xxxxxxx CME1000A-24xxxxxxx	100-240	50-60	11.8	Main output	21.6 Vdc	24Vdc	25.9 Vdc
					21.6Vdc~25.9Vdc, Normal: 41.7A & 1000.8W max.		
				Standby mode power (optional)	4.8Vdc	5Vdc	5.2Vdc
					2A	2A	1.9A
CUS1000M-36xxxxxxx CME1000A-36xxxxxxx	100-240	50-60	11.8	Main output	32.4 Vdc	36 Vdc	38.8Vdc
					32.4Vdc~38.8Vdc, Normal: 27.8A & 1000.8W max.		
				Standby mode power (optional)	4.8Vdc	5Vdc	5.2Vdc
					2A	2A	1.9A
CUS1000M-48xxxxxxx CME1000A-48xxxxxxx	100-240	50-60	11.8	Main output	43.2Vdc	48 Vdc	51.8Vdc
					43.2Vdc~51.8Vdc, Normal: 20.9A & 1003.2W max.		
				Standby mode power (optional)	4.8Vdc	5Vdc	5.2Vdc
					2A	2A	1.9A
Remark 1: Operating temp.: up to +70ºC (operating temperature depending on equipment's load, mounting position, for details refer to instruction manual).							

Definition of various:

CUS800My-zxxxxxxx, CME800Ay-zxxxxxxx, CUS1000My-zxxxxxxx, CME1000Ay-zxxxxxxx

(y = blank; z = 12,24,36,48; xxxxxxx = /CO, /CO2, /G, /SF, /CQC, other alphanumeric character, symbol or blank)

Variable:	Suffix	Description
y	blank	Denotes for standard model
z	12,24,36,48	Denotes for output voltage
xxxxxxx	blank	Denotes for standard model
	/CO	Denotes for single side PWB Coating
	/CO2	Denotes for double side PWB Coating
	/G	Denotes for low earth Leakage current
	/SF	Denotes for single fuse
	/CQC	Denotes for CQC approval
	other alphanumeric character, symbol	For market purposes, no construction differences and no impact.
Note: These suffixes may be used together (e.g. /G, /GCO).		