Ref. Certif. No.

DE 2-026587-M2

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, 214028 Wuxi, Jiangsu, P.R. China
Name and address of the manufacturer	TDK-Lambda (China) Electronics Co., Ltd. No. 95, Zhujiang Road, Xinwu District, 214028 Wuxi, Jiangsu, P.R. China
Name and address of the factory	See additional page(s)
Ratings and principal characteristics	Rated Input/Output: Refer to the test report for details. Protection Class: For not classified ME equipment
Trademark (if any)	TDK-Lambda
Customer's Testing Facility (CTF) Stage used	N/A
Model / Type Ref.	CUS600M1-zxxxxxxx, CME600A1-zxxxxxxx, CUS500M1-zxxxxxxx, CME500A-zxxxxxxx (z, xxxxxxx = refer to the test report)
Additional information (if necessary may also be reported on page 2)	The risk management requirements of the standard were not addressed. For model differences, refer to the report. Re-issue of DE 2-026587-M1 dated 15.09.2020, due to second modification.
A sample of the product was tested and found to be in conformity with	IEC 60601-1:2005+Corrigendum 1+Corrigendum 2+A1
As shown in the Test Report Ref. No. which forms part of this Certificate	50322508 003

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: 2020-11-20

Signature: Hongyan Yu

10/0861 CB 06/2019-rk

1. Zhangjiagang Hua Yang
   Electronics Co., Ltd.
   Zhao Feng Industrial Zone
   Leyu Town
   215622 Zhangjiagang, Jiangsu, P.R. China

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

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

Additional information (if necessary) Report Ref. No. : 50322508 003

Date: 2020-11-20 Signature: Hongyan Yu

Test Report issued under the responsibility of:

TÜVRheinland®

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

Report Number..... :	50322508 003
Date of issue ..... :	2020-11-19
Total number of pages ..... :	50 (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

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.

Test item description .....:	Switching Power Supply
Trade Mark.....:	TDK·Lambda
Manufacturer.....:	Same as applicant
Model/Type reference.....:	CUS600M1-**zxxxxxxx**, CME600A1-**zxxxxxxx**, CUS500M1-**zxxxxxxx**, CME500A-**zxxxxxxx** (**z** = 12, 19, 24, 28, 32, 36 or 48; **xxxxxxx** = /T, /J, /M, /C, /C2, /SF, /G, /EF, other alphanumeric character, symbol or blank) Refer to page 12 for definition of variables
Ratings.....:	See the model list on pages 9-11 for details

Testing procedure and testing location:			
☒	**CB Testing Laboratory:**	TÜV Rheinland Shanghai Co., Ltd.	
Testing location/ address ..... :		No.177, 178, Lane 777 West Guangzhong Road, Jing'an District, Shanghai, China	
☐	**Associated CB Testing Laboratory:**		
Testing location/ address ..... :			
Tested by (name + signature)..... :		Sunny Sun (Technical Expert)	
Approved by (name + signature) ..... :		Mark Chen (Technical Reviewer)	
☐	**Testing procedure: TMP/CTF Stage 1:**	N/A	
Testing location/ address ..... :			
Tested by (name + signature)..... :			
Approved by (name + signature) ..... :			
☐	**Testing procedure: WMT/CTF Stage 2:**	N/A	
Testing location/ address ..... :			
Tested by (name + signature)..... :			
Witnessed by (name + signature) ..... :			
Approved by (name + signature) ..... :			
☐	**Testing procedure: SMT/CTF Stage 3 or 4:**	N/A	
Testing location/ address ..... :			
Tested by (name + signature)..... :			
Witnessed by (name + signature) ..... :			
Approved by (name + signature) ..... :			
Supervised by (name + signature)..... :			

List of Attachments (including a total number of pages in each attachment):
ATTACHMENT – Photo documentation (4 pages)

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

Summary of testing:

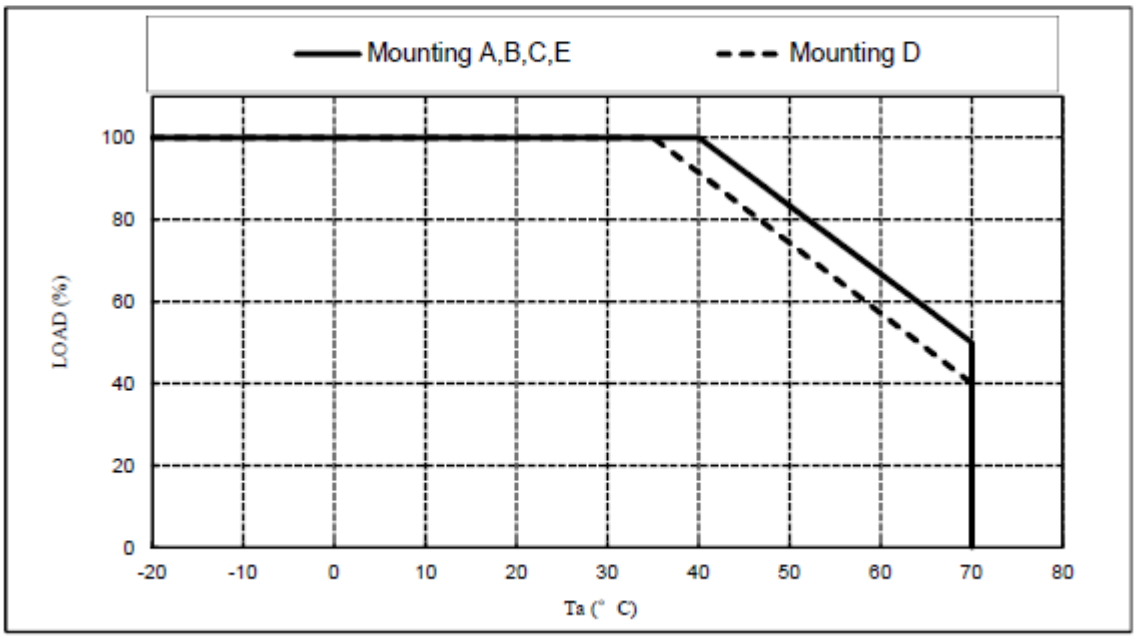
Tests performed (name of test and test clause):	**Testing location:**
All applicable tests as described in Test Case and Measurement Sections were performed on models CUS500M1-12 +, CUS500M1-19 +, CUS500M1-24 +, CUS500M1-28 +, CUS500M1-32 + and CUS500M1-48 + to represent other models. The maximum specified operation ambient temperature is 70°C. Specified ambient temperature for operation is according to manufacturer's specification. 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. The equipment is operated up to 5000m above sea level as declared by manufacturer. Clearances have been evaluated according to IEC 60601-1 table 8 with a multiplication factor of 1.29 throughout this report. The test samples are pre-production without serial numbers.	TÜV Rheinland Shanghai Co., Ltd. No.177, 178, Lane 777 West Guangzhong Road, Jing'an District, Shanghai, China

Derating Curve:

Convection cooling condition:

MODEL: CUS500M1-12/19/24/28/32/36/48

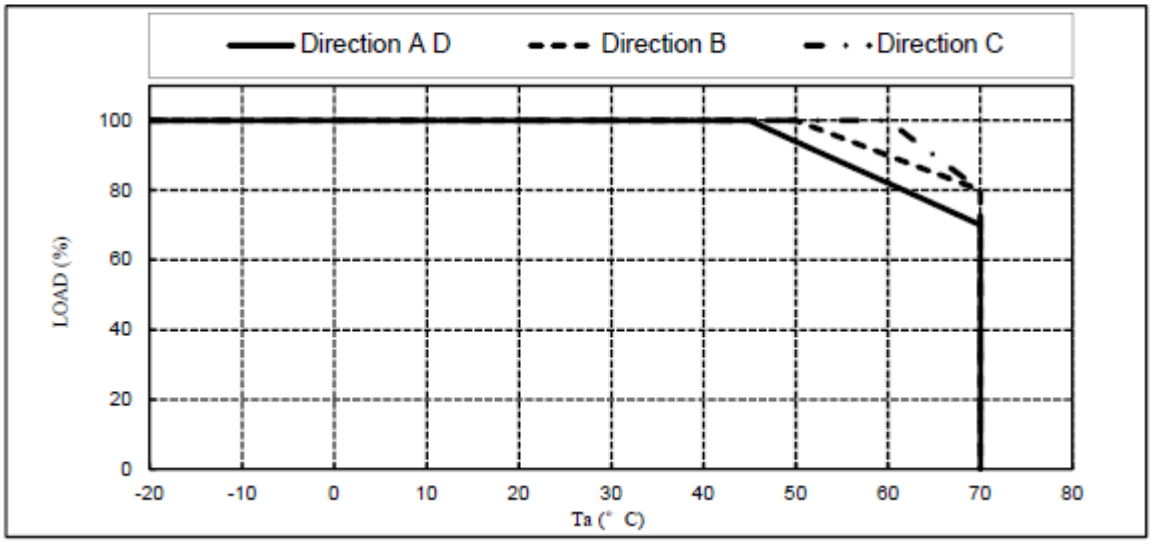
Ta (°C)	Mounting A B C E	Mounting D
	LOAD (%)	LOAD (%)
-20 - +35	100	100
40	100	91.4
50	83.3	74.3
60	66.7	57.1
70	50	40



Forced air cooling condition:

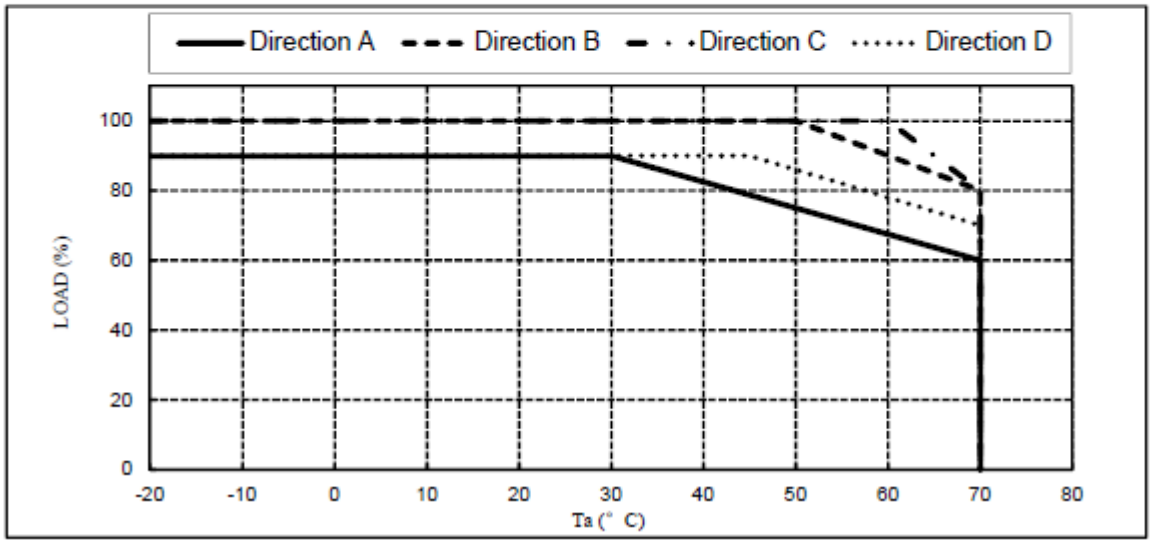
MODEL: CUS500M1-19/24/28/32/36/48

Ta (°C)	Direction A D	Direction B	Direction C
	LOAD (%)	LOAD (%)	LOAD (%)
-20 - +45	100	100	100
50	94	100	100
60	82	90	100
70	70	80	80



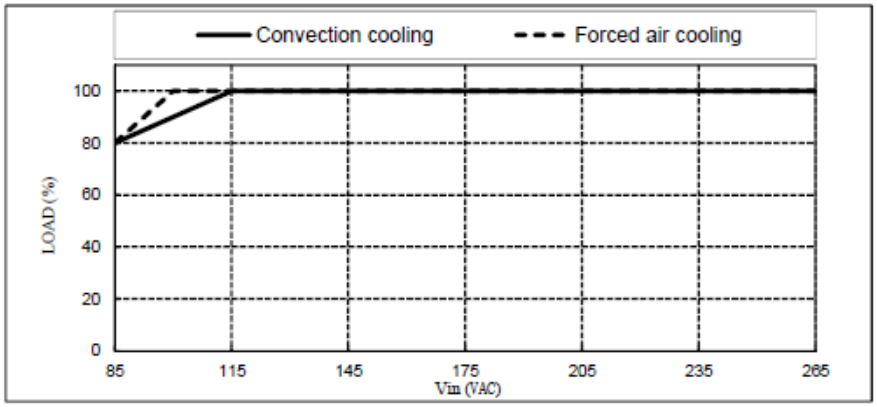
MODEL: CUS500M1-12

Ta (°C)	Direction A	Direction B	Direction C	Direction D
	LOAD (%)	LOAD (%)	LOAD (%)	LOAD (%)
-20 - +30	90	100	100	90
40	82.5	100	100	90
45	78.8	100	100	90
50	75	100	100	86
60	67.5	90	100	78
70	60	80	80	70

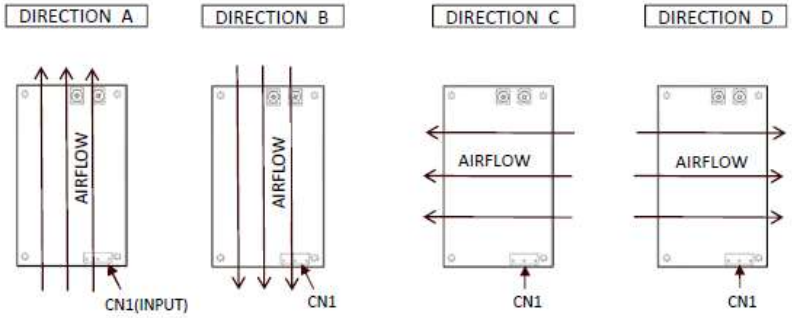


OUTPUT DERATING VERSUS INPUT VOLTAGE

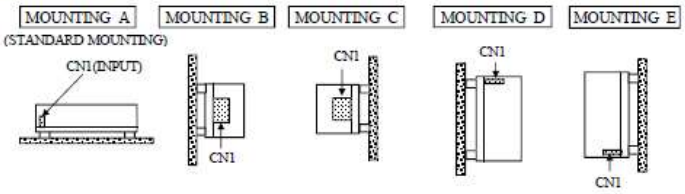
INPUT VOLTAGE (VAC)	LOAD (%)	
	CONVECTION COOLING	FORCED AIR COOLING
85	80	80
100	90	100
115~265	100	100



AIR FLOW DIRECTION



MOUNTING METHOD



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

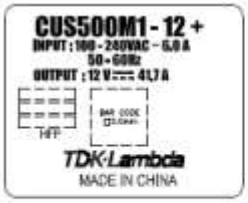
IEC 60601-1:2005 (Third Edition) + AM1 (2012)

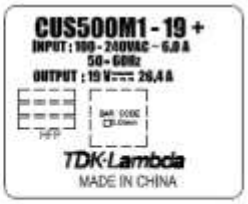
Refer to original CBTR 50322508 001 for details.

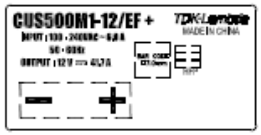
Copy of marking plate

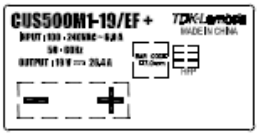
The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

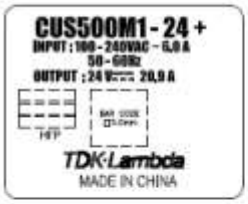
<Representative>

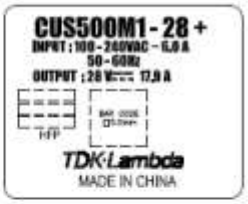


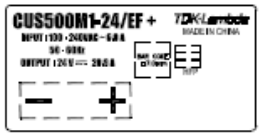


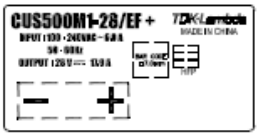


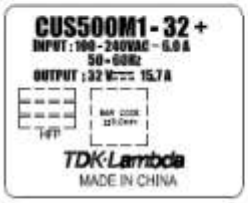


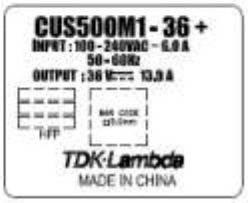


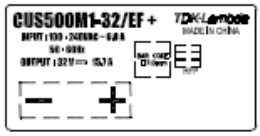


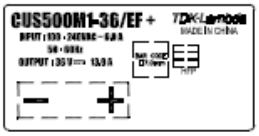


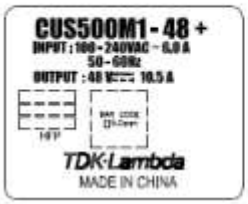


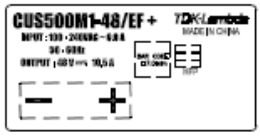












Remark: The rating labels of all models have the same design except for the model designation.

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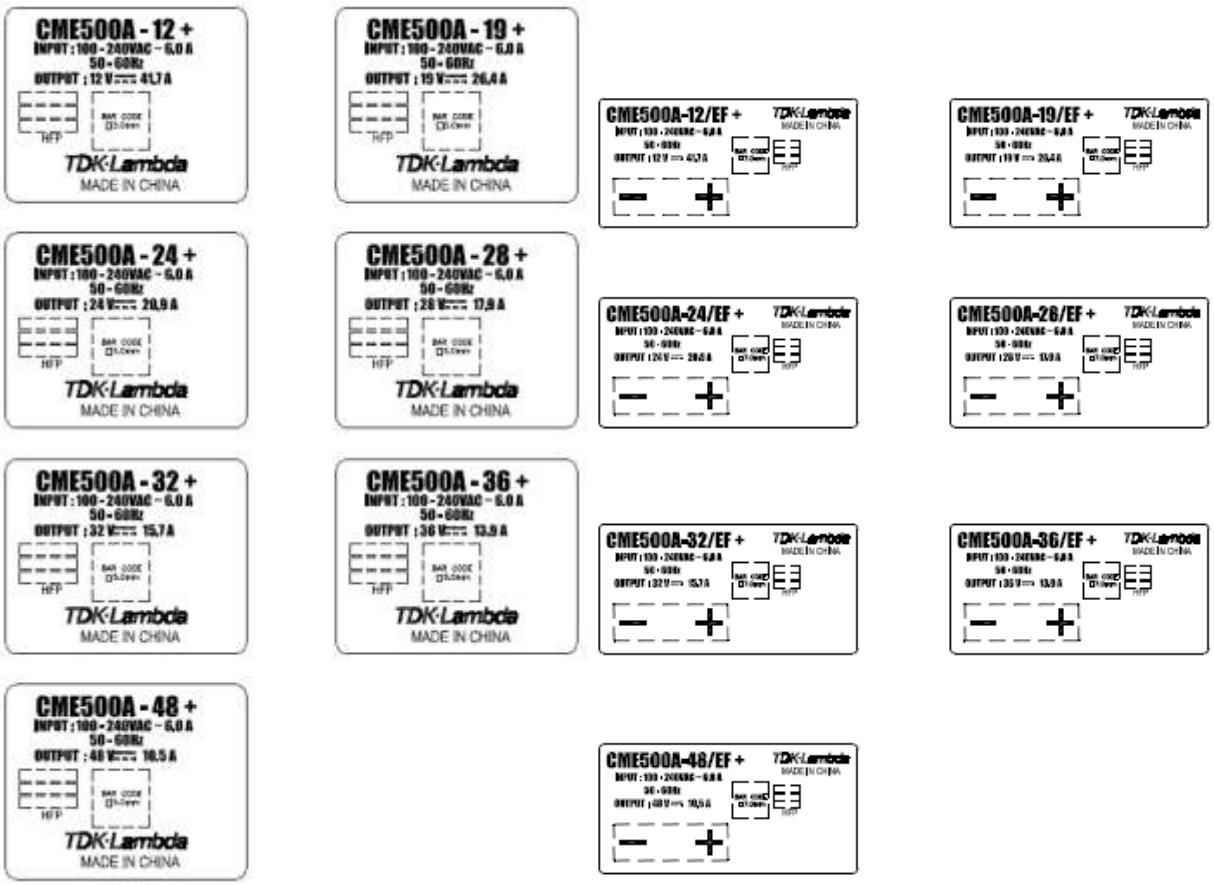

GENERAL INFORMATION	
Test item particulars (see also Clause 6):	For not classified ME equipment and a built-in, open frame type switching mode power supply
Classification of installation and use ..... :	Fixed
Device type (component/sub-assembly/ equipment/ system) ..... :	Sub-assembly
Intended use (Including 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
Testing	
Date of receipt of test item(s) ..... :	2020-08-17
Dates tests performed ..... :	2020-08-17 – 2020-08-28
Possible test case verdicts:	
- test case does not apply to the test object .... :	N/A
- test object does meet the requirement..... :	Pass (P)
- test object was not evaluated for the requirement.....:	N/E (collateral standards only)
- test object does not meet the requirement..... :	Fail (F)
Abbreviations used in the report:	
- normal condition ..... : N.C.	- single fault condition.....: S.F.C.
- means of Operator protection ..... : MOOP	- means of Patient protection ....: MOPP
General remarks:	
"(See Attachment #)" refers to additional information appended to the report. "(See appended table)" refers to a table appended to the report. The tests results presented in this report relate only to the object tested. This report shall not be reproduced except in full without the written approval of the testing laboratory. List of test equipment must be kept on file and available for review. Additional test data and/or information provided in the attachments to this report. **Throughout this report a ☐ comma / ☒ point is used as the decimal separator.**	
This Test Report Form is intended for the investigation of power supplies in accordance with IEC 60601-1:2005, 3rd 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 IECEE 02:2012

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. Zhangjiagang Hua Yang Electronics Co., Ltd. Zhao Feng Industrial Zone, Leyu Town 215622 Zhangjiagang, Jiangsu, China
2. TDK-Lambda (China) Electronics Co., Ltd. No. 95, Zhujiang Road, Xinwu District, 214028 Wuxi Jiangsu, China
3. TDK-Lambda Malaysia Sdn. Bhd PLO33, Kawasan Perindustrian Senai, 81400 Senai Johor Malaysia

General product information:

Refer to original report 50322508 001 for details.

For rating differences between the models see below tables:

Series Model	I/p voltage (Vac)	Freq (Hz)	I/p current (A)	Minimal output	Rated output (typical)	Maximum output
Convection cooling condition						
CUS600M1-12**xxxxxxx** CME600A1-12**xxxxxxx**	100-240	50-60	4.5	10.8Vdc	12Vdc	12.9Vdc
				10.8Vdc – 12.9Vdc Normal Rating: 33.4A, 400.8W Max. Peak Rating: 50A, 600W Max. (Dynamic)		
CUS600M1-19**xxxxxxx** CME600A1-19**xxxxxxx**	100-240	50-60	4.5	17.1Vdc	19Vdc	20.5Vdc
				17.1Vdc – 20.5Vdc Normal Rating: 21.1A, 400.9W Max. Peak Rating: 31.6A, 600.4W Max. (Dynamic)		
CUS600M1-24**xxxxxxx** CME600A1-24**xxxxxxx**	100-240	50-60	4.5	21.6Vdc	24Vdc	25.9Vdc
				21.6Vdc – 25.9Vdc, Normal Rating: 16.7A, 400.8W Max. Peak Rating: 25A, 600W Max. (Dynamic)		
CUS600M1-28**xxxxxxx** CME600A1-28**xxxxxxx**	100-240	50-60	4.5	25.2Vdc	28Vdc	30.2Vdc
				25.2Vdc – 30.2Vdc, Normal Rating: 14.3A, 400.4W Max. Peak Rating: 21.5A, 602W Max. (Dynamic)		
CUS600M1-32**xxxxxxx** CME600A1-32**xxxxxxx**	100-240	50-60	4.5	28.8Vdc	32Vdc	34.5Vdc
				28.8Vdc – 34.5Vdc, Normal Rating: 12.5A, 400W Max. Peak Rating: 18.8A, 601.6W Max. (Dynamic)		
CUS600M1-36**xxxxxxx**	100-240	50-60	4.5	32.4Vdc	36Vdc	38.8Vdc

CME600A1-36**xxxxxxx**				32.4Vdc – 38.8Vdc, Normal Rating: 11.1A, 399.6W Max. Peak Rating: 16.7A, 601.2W Max. (Dynamic)		
CUS600M1-48**xxxxxxx** CME600A1-48**xxxxxxx**	100-240	50-60	4.5	43.2 Vdc	48 Vdc	51.8 Vdc
				43.2Vdc – 51.8Vdc, Normal Rating: 8.4A, 403.2W Max. Peak Rating: 12.6A, 604.8W Max. (Dynamic)		
CUS500M1-12**xxxxxxx** CME500A-12**xxxxxxx**	**100-240**	**50-60**	**4.0**	**10.8 Vdc**	**12 Vdc**	**12.9 Vdc**
				10.8Vdc – 12.9Vdc, Normal rating: 25A, 300W Max. Peak rating: 41.7A, 500.4W Max. (Dynamic)		
CUS500M1-19**xxxxxxx** CME500A-19**xxxxxxx**	**100-240**	**50-60**	**4.0**	**17.1 Vdc**	**19 Vdc**	**20.5 Vdc**
				17.1Vdc – 20.5Vdc, Normal rating: 15.8A, 300.2W Max. Peak rating: 26.4A, 501.6W Max. (Dynamic)		
CUS500M1-24**xxxxxxx** CME500A-24**xxxxxxx**	**100-240**	**50-60**	**4.0**	**21.6 Vdc**	**24 Vdc**	**25.9 Vdc**
				21.6Vdc – 25.9Vdc, Normal Rating: 12.5A, 300W Max. Peak Rating: 20.9A, 501.6W Max. (Dynamic)		
CUS500M1-28**xxxxxxx** CME500A-28**xxxxxxx**	**100-240**	**50-60**	**4.0**	**25.2 Vdc**	**28 Vdc**	**30.2 Vdc**
				25.2Vdc – 30.2Vdc, Normal Rating: 10.7A, 299.6W Max. Peak Rating: 17.9A, 501.2W Max. (Dynamic)		
CUS500M1-32**xxxxxxx** CME500A-32**xxxxxxx**	**100-240**	**50-60**	**4.0**	**28.8Vdc**	**32Vdc**	**34.5Vdc**
				28.8Vdc – 34.5Vdc, Normal Rating: 9.4A, 300.8W Max. Peak Rating: 15.7A, 502.4W Max. (Dynamic)		
CUS500M1-36**xxxxxxx** CME500A-36**xxxxxxx**	**100-240**	**50-60**	**4.0**	**32.4Vdc**	**36Vdc**	**38.8Vdc**
				32.4Vdc – 38.8Vdc, Normal Rating: 8.3A, 298.8W Max. Peak Rating: 13.9A, 500.4W Max. (Dynamic)		
CUS500M1-48**xxxxxxx** CME500A-48**xxxxxxx**	**100-240**	**50-60**	**4.0**	**43.2Vdc**	**48Vdc**	**51.8Vdc**
				43.2Vdc – 51.8Vdc, Normal Rating: 6.3A, 302.4W Max. Peak Rating: 10.5A, 504W Max. (Dynamic)		
Forced air cooling condition (airflow: air velocity 2.7m/s & air volume 28.6CFM)						
CUS600M1-12**xxxxxxx**	100-240	50-60	7.0	10.8Vdc	12Vdc	12.9Vdc

CME600A1-12**xxxxxxx**				50A	50A	46.6A
CUS600M1-19**xxxxxxx** CME600A1-19**xxxxxxx**	100-240	50-60	7.0	17.1Vdc	19Vdc	20.5Vdc
				31.6A	31.6A	29.3A
CUS600M1-24**xxxxxxx** CME600A1-24**xxxxxxx**	100-240	50-60	7.0	21.6Vdc	24Vdc	25.9Vdc
				25A	25A	23.2A
CUS600M1-28**xxxxxxx** CME600A1-28**xxxxxxx**	100-240	50-60	7.0	25.2Vdc	28Vdc	30.2Vdc
				21.5A	21.5A	20.0A
CUS600M1-32**xxxxxxx** CME600A1-32**xxxxxxx**	100-240	50-60	7.0	28.8Vdc	32Vdc	34.5Vdc
				18.8A	18.8A	17.5A
CUS600M1-36**xxxxxxx** CME600A1-36**xxxxxxx**	100-240	50-60	7.0	32.4Vdc	36Vdc	38.8Vdc
				16.7A	16.7A	15.5A
CUS600M1-48**xxxxxxx** CME600A1-48**xxxxxxx**	100-240	50-60	7.0	43.2Vdc	48Vdc	51.8Vdc
				12.6A	12.6A	11.7A
CUS500M1-12**xxxxxxx** CME500A-12**xxxxxxx**	**100-240**	**50-60**	**6.0**	**10.8Vdc**	**12Vdc**	**12.9Vdc**
				41.7A	**41.7A**	**38.8A**
CUS500M1-19**xxxxxxx** CME500A-19**xxxxxxx**	**100-240**	**50-60**	**6.0**	**17.1Vdc**	**19Vdc**	**20.5Vdc**
				26.4A	**26.4A**	**24.5A**
CUS500M1-24**xxxxxxx** CME500A-24**xxxxxxx**	**100-240**	**50-60**	**6.0**	**21.6Vdc**	**24Vdc**	**25.9Vdc**
				20.9A	**20.9A**	**19.4A**
CUS500M1-28**xxxxxxx** CME500A-28**xxxxxxx**	**100-240**	**50-60**	**6.0**	**25.2Vdc**	**28Vdc**	**30.2Vdc**
				17.9A	**17.9A**	**16.6A**
CUS500M1-32**xxxxxxx** CME500A-32**xxxxxxx**	**100-240**	**50-60**	**6.0**	**28.8Vdc**	**32Vdc**	**34.5Vdc**
				15.7A	**15.7A**	**14.6A**
CUS500M1-36**xxxxxxx** CME500A-36**xxxxxxx**	**100-240**	**50-60**	**6.0**	**32.4Vdc**	**36Vdc**	**38.8Vdc**
				13.9A	**13.9A**	**12.9A**
CUS500M1-48**xxxxxxx** CME500A-48**xxxxxxx**	**100-240**	**50-60**	**6.0**	**43.2Vdc**	**48Vdc**	**51.8Vdc**
				10.5A	**10.5A**	**9.8A**
Remark: Operating temp.: up to +70ºC (operating temperature depending on equipment's load, mounting position, for details refer to instruction manual).						

Description of changes:

The previous approved models were modified as following:

- Add additional models CUS500M1-**zxxxxxxx**, CME500A-**zxxxxxxx** (**z** = 12, 19, 24, 28, 32, 36 or 48; **xxxxxxx** = /T, /J, /M, /C, /C2, /SF, /G, /EF, other alphanumeric character, symbol or blank), which are similar to original models CUS600M1-**zxxxxxxx**, CME600A1-**zxxxxxxx** with following differences:
  - Rated input current, output ratings.
  - Add alternate heatsink combination 2. See below table for details:

Parts	Combination 1 (CUS600M1 heatsink)	Combination 2 (tested in this report)
KFA1 (Pri. side)	CA878-32-01x	CA922-32-01x
KFA2 (Pri. side)	CA878-32-03x	without

KFA3 (Sec. side)	CA878-32-05x (12V) (optional) CA878-32-04x (others) (optional)	without
HS201 & HS204 (Sec. side)	TZDD3271 (optional)	without
KKE1 (Sec. side)	CA878-33-01x (optional)	without

- Component parameter adjustment for MOSFET (Q1), Diode (D1), Primary Electrolytic Capacitor (C6) and Resistor (R108).

- Add additional factory TDK-Lambda Malaysia Sdn. Bhd, see factory list on page 9 for details.
- Correct typo error of external creepage from 5.0 mm to 8.0 mm for optocoupler.

All applicable tests were performed. Refer to above model list, test case and measurement section for details.

Definition of variable(s):

CUS600M1-**zxxxxxxx**, CME600A1-**zxxxxxxx**, CUS500M1-**zxxxxxxx**, CME500A-**zxxxxxxx**
(**z** = 12, 19, 24, 28, 32, 36 or 48; **xxxxxxx** = /T, /J, /M, /C, /C2, /SF, /G, /EF, other alphanumeric character, symbol or blank)

Variable:	Range of variable:	Content:
z	12, 19, 24, 28, 32, 36 or 48	Denoting output voltage from 12 Vdc to 48 Vdc.
xxxxxxx	blank	Denoting for Standard model.
	/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.
	other alphanumeric character, symbol	Used for market purposes, no construction differences and no safety impact.

History of amendments and modifications:

Ref. No. 50322508 001, dated 2019-12-18 (original test report)
Ref. No. 50322508 002, dated 2020-09-11 (1st modification)
Ref. No. 50322508 003, dated “see cover page” (2nd modification)

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..... :	☒ 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}					
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Supplementary information:

Same as original models, refer to original report 50322508 001 for details.

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.