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. .....:	15081719 002
Date of issue .....:	2016-09-29
Total number of pages.....:	80
Name of Testing Laboratory preparing the Report.....:	TÜV Rheinland (Shanghai) Co., Ltd. No.177, 178, Lane 777, West Guangzhong Road Zhabei District Shanghai CHINA
Applicant's name.....:	TDK-Lambda Corp. Nagaoka Technical Center
Address .....:	2704-1 Settaya-machi, Nagaoka-shi, NIIGATA 940-1195, JAPAN
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 ..... :	CUS200M-**zxxxxxxx**; CME200A-**zxxxxxxx**; CUS150M1-**zxxxxxxx**; CME150A-**zxxxxxxx** (**z** = 12, 18, 24, 36 or 48; **xxxxxxx** = T, M, MR, R, J, JR, L, A, CO2, S1, other alphanumeric character, symbol or blank) Refer to pages 8-9 for definition of variables
Ratings ..... :	AC input: 100-240V, 3.0A, 50-60Hz (for CUS200M and CME200A) 100-240V, 1.8A, 50-60Hz (for CUS150M1 and CME150A) DC output: See the model list on page 7 and 8 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 Zhabei District Shanghai CHINA	
☐ **Associated CB Testing Laboratory:**		
Testing location/ address ..... :		
Tested by (name + signature) ..... :	Sunny Sun	
Approved by (name + signature) ..... :	Mark Chen	
☐ **Testing procedure: TMP/CTF Stage 1:**		
Testing location/ address ..... :		
Tested by (name + signature) ..... :		
Approved by (name + signature) ..... :		
☐ **Testing procedure: WMT/CTF Stage 2:**		
Testing location/ address ..... :		
Tested by (name + signature) ..... :		
Witnessed by (name + signature) ..... :		
Approved by (name + signature) ..... :		
☐ **Testing procedure: SMT/CTF Stage 3 or 4:**		
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 1 - Technical Documentation (16 pages)
- Attachment 2 - Photo Documentation (8 pages)

Summary of testing:

All applicable tests as described in Test Case and Measurement Sections were performed.

The maximum specified operation ambient temperature is 70°C.

Specified ambient temperature for operation is according to manufacturer's specification.(see Attachment 1 – Technical Documentation for chart of convection cooling and forced air cooling)

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.

Tests performed (name of test and test clause):	**Testing location:**
• 4.11 Power input • 5.7 Humidity pre-conditioning • 7.1.3 Marking durability • 8.4.2 ACCESSIBLE PARTS and APPLIED PARTS • 8.5.4 Working voltage • 8.7.4 Leakage currents • 8.8.3 Dielectric strength • 11.1 Excessive temperatures • 13 Hazardous situations and fault conditions • 15.5 Mains supply transformers and transformers providing safety isolation	TÜV Rheinland (Shanghai) Co., Ltd. No.177, 178, Lane 777, West Guangzhong Road Zhabei District Shanghai CHINA

Summary of compliance with National Differences

List of countries addressed:

AT, KR, GB, SE
*(CA, US)

Explanation of used codes:
AT=Austria; GB=United Kingdom; KR = Republic of Korea; SE=Sweden
*(CA=Canada; US = United States of America)

* National differences to IEC 60601-1:2005 evaluated

The product fulfils the requirements of

EN 60601-1:2006+A11:2011+A1:2013+A12:2014

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

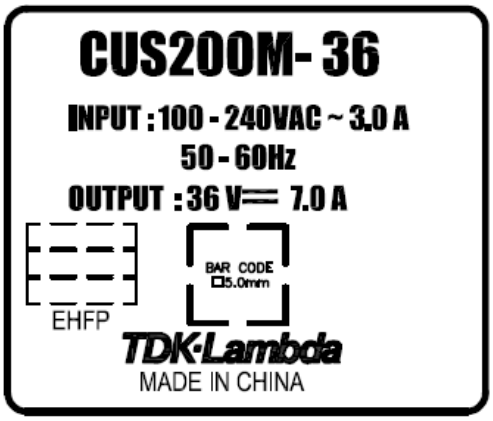
CAN/CSA-C22.2 NO. 60601-1:14

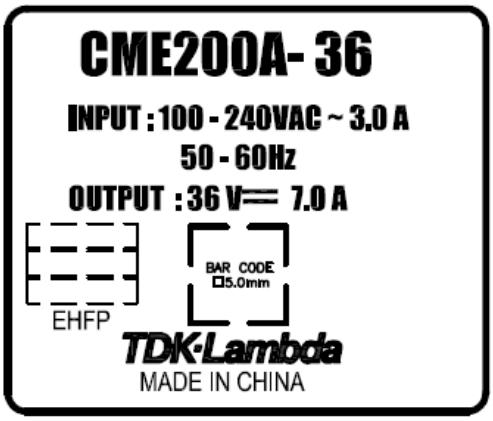
CAN/CSA-C22.2 NO. 60601-1-08 (R2013)

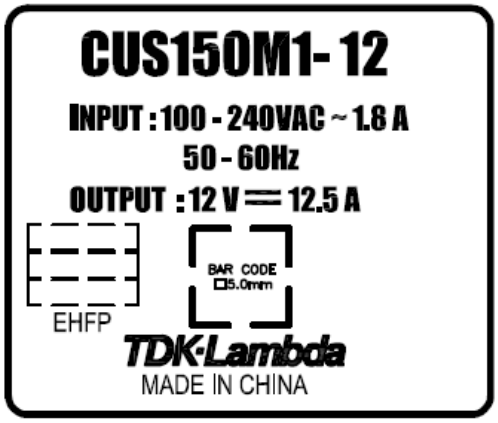
Copy of marking plate

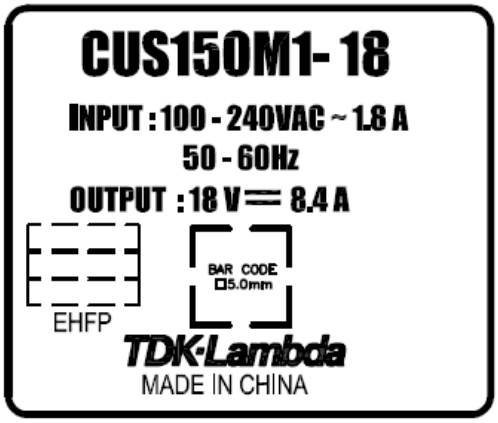
The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

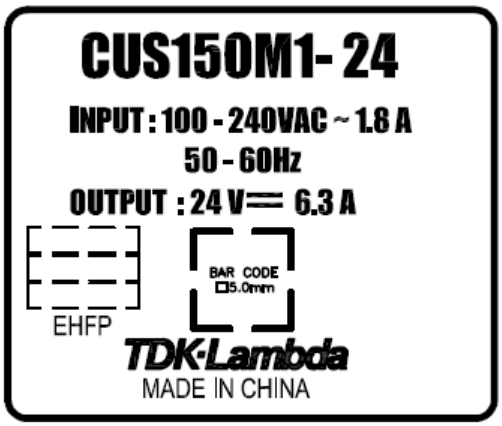
New models

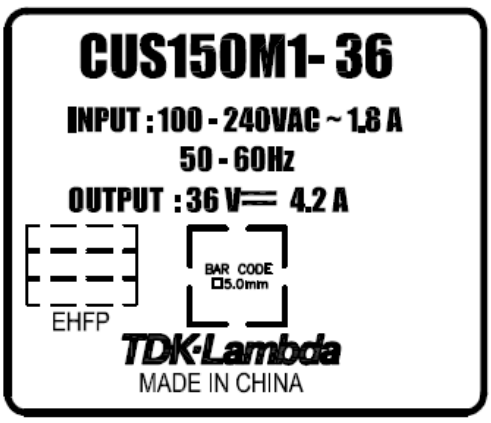




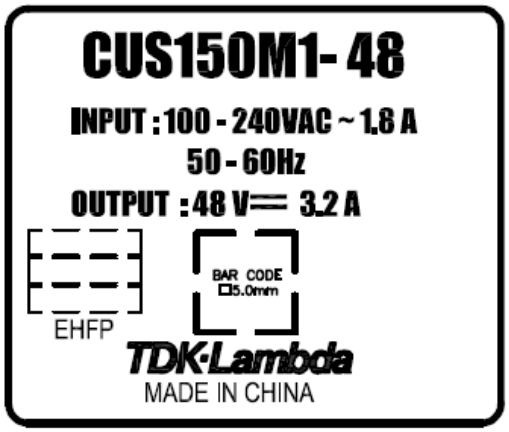


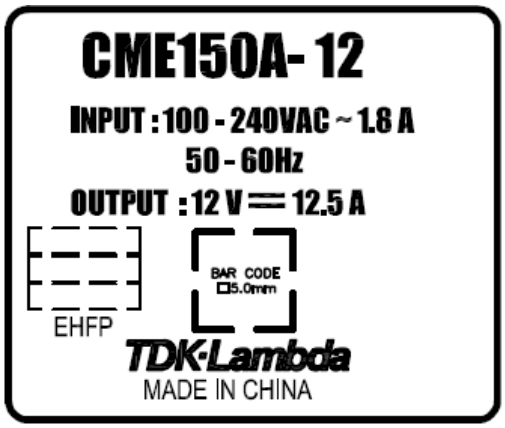


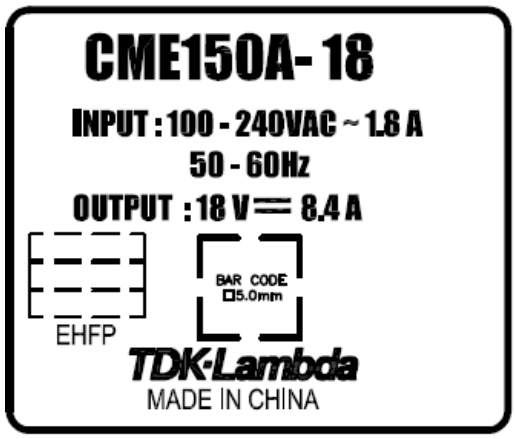


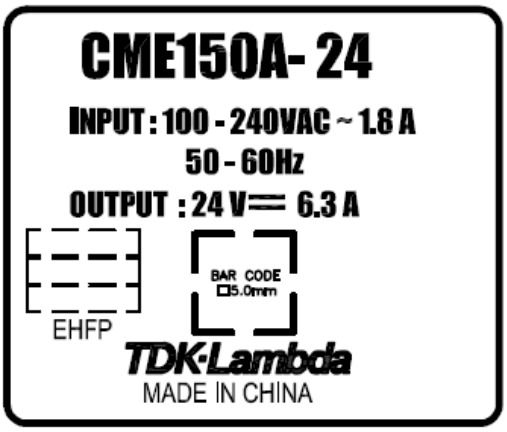


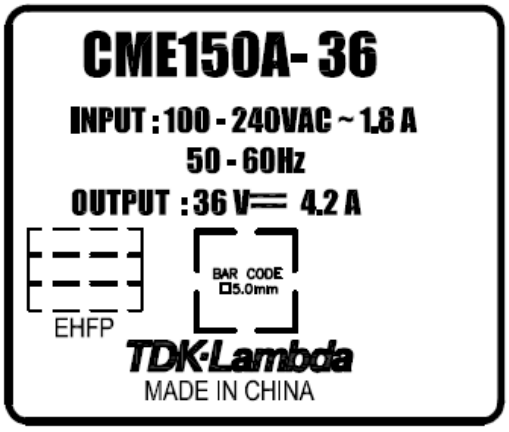
Cont.

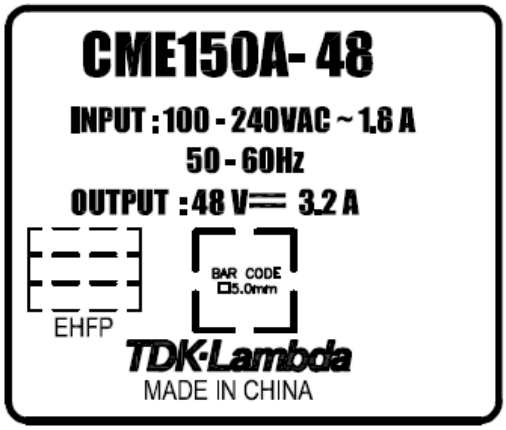

CUS150M1-48
INPUT : 100 - 240VAC ~ 1.8 A
50 - 60Hz
OUTPUT : 48 V⎓ 3.2 A
EHFP
BAR CODE
□5.0mm
TDK·Lambda
MADE IN CHINA


CME150A-12
INPUT : 100 - 240VAC ~ 1.8 A
50 - 60Hz
OUTPUT : 12 V⎓ 12.5 A
EHFP
BAR CODE
□5.0mm
TDK·Lambda
MADE IN CHINA


CME150A-18
INPUT : 100 - 240VAC ~ 1.8 A
50 - 60Hz
OUTPUT : 18 V⎓ 8.4 A
EHFP
BAR CODE
□5.0mm
TDK·Lambda
MADE IN CHINA


CME150A-24
INPUT : 100 - 240VAC ~ 1.8 A
50 - 60Hz
OUTPUT : 24 V⎓ 6.3 A
EHFP
BAR CODE
□5.0mm
TDK·Lambda
MADE IN CHINA


CME150A-36
INPUT : 100 - 240VAC ~ 1.8 A
50 - 60Hz
OUTPUT : 36 V⎓ 4.2 A
EHFP
BAR CODE
□5.0mm
TDK·Lambda
MADE IN CHINA


CME150A-48
INPUT : 100 - 240VAC ~ 1.8 A
50 - 60Hz
OUTPUT : 48 V⎓ 3.2 A
EHFP
BAR CODE
□5.0mm
TDK·Lambda
MADE IN CHINA

GENERAL INFORMATION	
Test item particulars (see also Clause 6):	For Class I 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) ..... :	2016-07-06
Dates tests performed ..... :	2016-09-16 to 2016-09-26
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. Wuxi TDK-Lambda Electronics Co., Ltd. No. 6 Xing Chuang Er Lu, 214028 Wuxi, Jiangsu, China
2. Zhangjiagang Hua Yang Electronics Co., Ltd. Zhao Feng Industrial Zone, Leyu Town, 215622 Zhangjiagang, Jiangsu, China

General product information:

Refer to original report 15081719 001.

For Construction B Models:

Use single PCB layout (ZCCB166) for all models. All models are identical, except of the optional chassis, cover, turns of Transformer and the rating of some components which results in different output ratings.

Schematic and PCB layout for models CUS150M1 & CME150A are identical to models CUS200M & CME200A except for output power and some components rating.

Model CME150A-**zxxxxxxx** is identical to Construction B of model CUS150M1-**zxxxxxxx** except for model name.

See Model List below 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						
CUS200M-12 xxxxxxx CME200A-12 xxxxxxx	100-240	50-60	3.0	11.4Vdc	12Vdc	12.6Vdc
				16.7A	16.7A	15.9A
CUS200M-18 xxxxxxx CME200A-18 xxxxxxx	100-240	50-60	3.0	17.1Vdc	18Vdc	19.8Vdc
				11.2A	11.2A	10.2A
CUS200M-24 xxxxxxx CME200A-24 xxxxxxx	100-240	50-60	3.0	22.8Vdc	24Vdc	26.4Vdc
				8.4A	8.4A	7.6A
CUS200M-36 xxxxxxx CME200A-36 xxxxxxx	100-240	50-60	3.0	34.2Vdc	36Vdc	39.6Vdc
				5.57A	5.57A	5.06A
CUS200M-48 xxxxxxx CME200A-48 xxxxxxx	100-240	50-60	3.0	45.6Vdc	48Vdc	52.8Vdc
				4.2A	4.2A	3.8A
CUS150M1-12xxxxxxx CME150A-12 xxxxxxx	100-240	50-60	1.8	11.4Vdc	12Vdc	12.6Vdc
				12.5A	12.5A	11.9A
CUS150M1-18xxxxxxx CME150A-18 xxxxxxx	100-240	50-60	1.8	17.1Vdc	18Vdc	19.8Vdc
				8.4A	8.4A	7.6A
CUS150M1-24xxxxxxx CME150A-24 xxxxxxx	100-240	50-60	1.8	22.8Vdc	24Vdc	26.4Vdc
				6.3A	6.3A	5.7A
CUS150M1-36xxxxxxx CME150A-36 xxxxxxx	100-240	50-60	1.8	34.2Vdc	36Vdc	39.6Vdc
				4.2A	4.2A	3.8A
CUS150M1-48xxxxxxx CME150A-48 xxxxxxx	100-240	50-60	1.8	45.6Vdc	48Vdc	52.8Vdc
				3.2A	3.2A	2.9A

Series Model	I/p voltage (Vac)	Freq (Hz)	I/p current (A)	Minimal output	Rated output (typical)	Maximum output
Forced air cooling condition(airflow: air velocity 1.5m/s)						
CUS200M-12 xxxxxxx CME200A-12 xxxxxxx	100-240	50-60	3.0	11.4Vdc	12Vdc	12.6Vdc
				21A	21A	20A
CUS200M-18 xxxxxxx CME200A-18 xxxxxxx	100-240	50-60	3.0	17.1Vdc	18Vdc	19.8Vdc
				14A	14A	12.7A
CUS200M-24 xxxxxxx CME200A-24 xxxxxxx	100-240	50-60	3.0	22.8Vdc	24Vdc	26.4Vdc
				10.5A	10.5A	9.5A
CUS200M-36 xxxxxxx CME200A-36 xxxxxxx	100-240	50-60	3.0	34.2Vdc	36Vdc	39.6Vdc
				7A	7A	6.4A
CUS200M-48 xxxxxxx CME200A-48 xxxxxxx	100-240	50-60	3.0	45.6Vdc	48Vdc	52.8Vdc
				5.3A	5.3A	4.8A

Description of change(s):

1. Add new model CUS200M-36 xxxxxxx and CME200A-36 xxxxxxx for Construction B models.
2. Add new model name CUS150M1 series and CME150A series for Construction B models.
3. Re-new **critical components list.**

For the above described change(s) the following was considered to be necessary:

Change	Testing	Comments
1	4.11 Power input 8.5.4 Working voltage	Rest testing have been covered in previous series, no further testing was deemed necessary.
2	See “Tests performed” on page 3	See “Summary of testing” and appended tables for details.
3	N/A	See table 8.10 for details.

History of amendments and modifications:

Ref. No. 15081719 001, dated 23 November, 2015 (original test report)
Ref. No. 15081719 002, dated 29 September, 2016 (1st modification)

Additional Information

- The input circuit includes only one fuse in the Line 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.

Definition of variable(s):

CUS200M-**zxxxxxxx**; CME200A-**zxxxxxxx**; CUS150M1-**zxxxxxxx**; CME150A-**zxxxxxxx**
(**z** = 12, 18, 24, 36 or 48; **xxxxxxx** = T, M, MR, R, J, JR, L, A, CO2, S1, other alphanumeric character, symbol or blank)

Variable:	Range of variable:	Content:
z	12, 18, 24, 36 or 48	Denotes for output voltage
xxxxxxx	T	Denotes for Terminal block connector
	M	Denotes for Molex connector
	MR	Denotes for Molex connector in reverse direction
	R	Denotes for JST connector or TE connectivity Connector in reverse direction
	J	Denotes for JST connector
	JR	Denotes for JST connector in reverse direction

	L	Denotes for chassis
	A	Denotes for cover & chassis
	CO2	Denotes PWB coating
	S1	Denotes for two pins input connector & FG Tap
	other alphanumeric character, symbol	For market purposes, no construction differences and no safety impact.
	blank	Denotes for JST connector or TE connectivity Connector