Test Report issued under the responsibility of:

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

Report Number..... :	**T223-0347/14**
Date of issue ..... :	**2014-12-05**
Total number of pages ..... :	**182 pages**
Name of Testing Laboratory preparing the Report ..... :	**SIQ – Slovenian Institute of Quality and Metrology** **Testing Laboratory is accredited by Slovenian Accreditation, Reg. No.: LP-009**
Applicant's name ..... :	**TDK-Lambda UK Limited**
Address..... :	**Kingsley Avenue, Ilfracombe, Devon EX34 8ES, United Kingdom**
Test specification:	
Standard ..... :	IEC 60601-1:2005 (3rd Ed.) + CORR. 1 (2006) + CORR. 2 (2007) + A1:2012
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

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 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..... :	Switch mode power supply for building-in
Trade Mark..... :	TDK-Lambda
Manufacturer ..... :	TDK-Lambda UK Limited Kingsley Avenue, Ilfracombe, Devon EX34 8ES, United Kingdom
Model/Type reference..... :	ZMS100-X/E/T/J or CUS100MA-X/E/T/J
	Where: -X = Output Voltage as detailed in the Output Parameters tables below. /E = Curve B radiated for emc /T = Earth fast-on terminal not fitted /J = JST input and/or output connectors fitted
	Type references may be prefixed by SP and/or NS # followed by / or - (where # may be any number of characters indicating non-safety related model differences)
Ratings..... :	Input: 100 – 240 Vac; 47 – 63 Hz; 2,2 A max.
	Output:

Forced air cooling

Model	Output voltage (V⎓)	Output current (A)	Output power (W)
ZMS100-12	12	8,4	100,8
ZMS100-15	15	6,7	100,5
ZMS100-24	24	4,2	100,8
ZMS100-28	28	3,6	100,8
ZMS100-36	36	2,8	100,8
ZMS100-48	48	2,1	100,8

Convection cooling

ZMS100-12	12	6,7	80,4
ZMS100-15	15	5,4	81
ZMS100-24	24	3,4	81,6
ZMS100-28	28	2,9	81,2
ZMS100-36	36	2,25	81
ZMS100-48	48	1,67	80,2

Testing procedure and testing location:		
☒ CB Testing Laboratory:	SIQ – Slovenian Institute of Quality and Metrology	
Testing location/ address ..... :	Tržaška cesta 2, SI-1000 Ljubljana, Slovenia	
☐ Associated CB Testing Laboratory:		
Testing location/ address ..... :		
Tested by (name + signature)..... :	Janez Vidmar	
Approved by (name + signature) ..... :	Gregor Schoss	
☐ 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):

1. **Test Report (130 pages)**
2. **National Differences to IEC 60601-1:2005 + A1:2012 – Enclosure No. 1 (24 pages)**
3. **Photo documentation – Enclosure No. 2 (7 pages)**
4. **Schematics, layouts and transformer drawings – Enclosure No. 3 (21 pages)**

Summary of testing

Tests performed (name of test and test clause):	**Testing location:**
4.11 Power Input	**SIQ – Slovenian Institute of Quality and Metrology**
7.1.2 Legibility of marking	**Tržaška cesta 2**
7.1.3 Durability of marking	**SI-1000 Ljubljana, Slovenia**
8.4.2 c) Limitation of voltage current or energy	
8.4.3 ME equipment intended to be connected to a power source by a plug	
8.5.4 Working voltage Measurement	
8.6.4 Impedance and current- carrying capability of protective earth connections	
8.7.4.5 Earth Leakage Current	
8.7.4.6 Touch Current	
8.8.3 Dielectric Strength test of solid insulation materials with safety functions	
8.9.2 Short circuits in Mains part over creepage and clearance distances	
8.9.4 Measurement of creepage distances and air clearances	
11.1 Excessive temperatures in ME EQUIPMENT	
13.2 Single Fault conditions	
15.3.2 Push test	
15.5.1.2 Transformer short circuit	
15.5.1.3 Transformer overload	
Evaluation of voltage limiting components in SELV circuits	

Summary of compliance with National Differences

List of countries addressed:

- **IEC 60601-1:2005 + A1:2012**

  No national differences for IEC 60601-1:2005 + A1:2012 declared.

- **IEC 60601-1:2005**

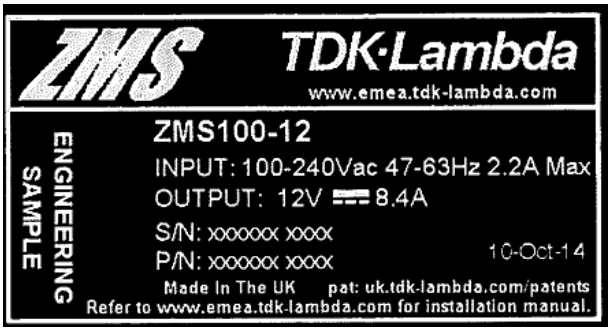
  List of countries addressed:

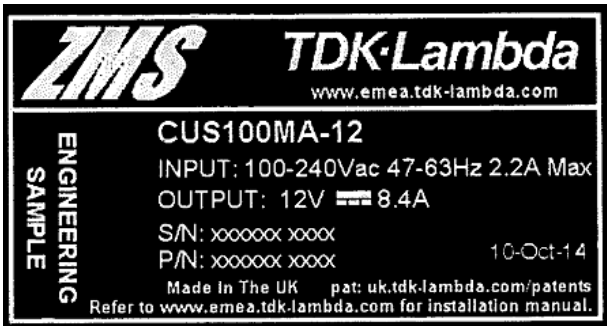
  - US NATIONAL DIFFERENCES to IEC 60601-1 Third edition
    National standard ANSI/AAMI ES60601-1:2005
  - CANADA NATIONAL DIFFERENCES to IEC 60601-1 Third edition
    National standard CAN/CSA-C22.2 No. 60601-1:08
  - SWITZERLAND NATIONAL DIFFERENCES to IEC 60601-1 Third edition
    National standard SN EN 60601-1:06
  - JAPAN NATIONAL DIFFERENCES to IEC 60601-1 Third edition
    National standard: JIS T0601-1:2012
  - REPUBLIC OF KOREA Differences to IEC 60601-1 Third edition
    National standard: KS C IEC 60601-1

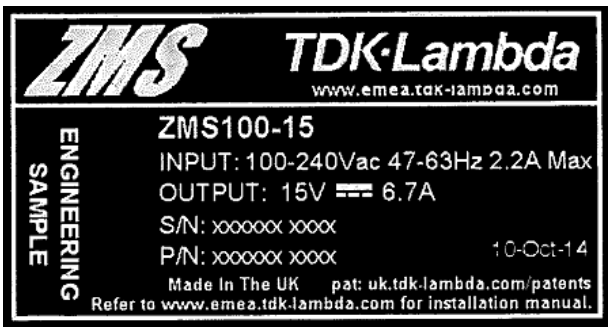
☒ The product fulfils the requirements of EN 60601-1:2006 + A11:2011

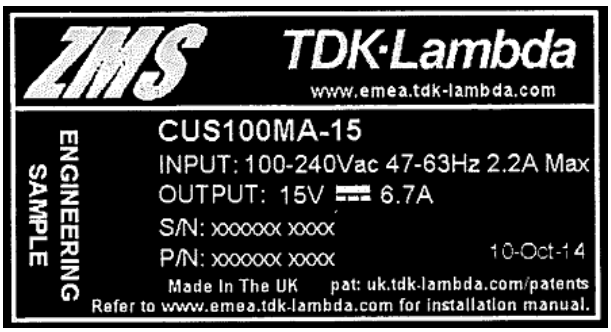
Copy of marking plate

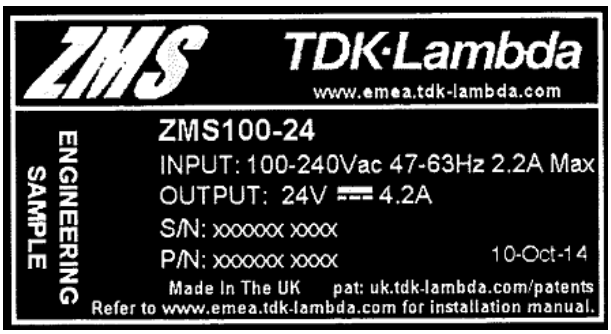
The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

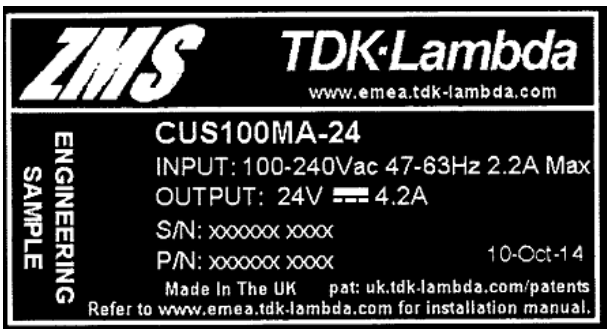


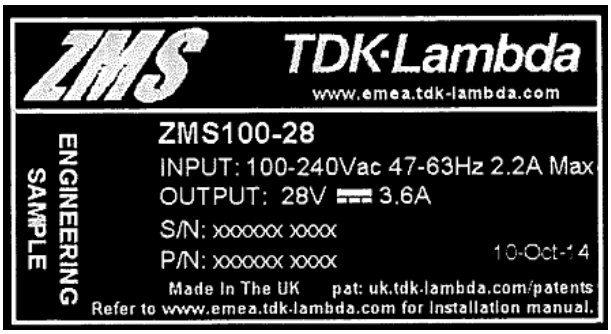


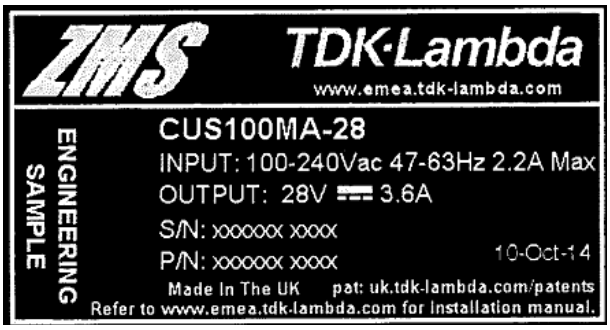













ZMS TDK·Lambda
www.emea.tdk-lambda.com
ENGINEERING SAMPLE
ZMS100-36
INPUT: 100-240Vac 47-63Hz 2.2A Max
OUTPUT: 36V ⎓ 2.8A
S/N: xxxxxx xxxx
P/N: xxxxxx xxxx
10-Oct-14
Made In The UK pat: uk.tdk-lambda.com/patents
Refer to www.emea.tdk-lambda.com for installation manual.
ZMS TDK·Lambda
www.emea.tdk-lambda.com
ENGINEERING SAMPLE
CUS100MA-36
INPUT: 100-240Vac 47-63Hz 2.2A Max
OUTPUT: 36V ⎓ 2.8A
S/N: xxxxxx xxxx
P/N: xxxxxx xxxx
10-Oct-14
Made In The UK pat: uk.tdk-lambda.com/patents
Refer to www.emea.tdk-lambda.com for installation manual.
ZMS TDK·Lambda
www.emea.tdk-lambda.com
ENGINEERING SAMPLE
ZMS100-48
INPUT: 100-240Vac 47-63Hz 2.2A Max
OUTPUT: 48V ⎓ 2.1A
S/N: xxxxxx xxxx
P/N: xxxxxx xxxx
10-Oct-14
Made In The UK pat: uk.tdk-lambda.com/patents
Refer to www.emea.tdk-lambda.com for installation manual.
ZMS TDK·Lambda
www.emea.tdk-lambda.com
ENGINEERING SAMPLE
CUS100MA-48
INPUT: 100-240Vac 47-63Hz 2.2A Max
OUTPUT: 48V ⎓ 2.1A
S/N: xxxxxx xxxx
P/N: xxxxxx xxxx
10-Oct-14
Made In The UK pat: uk.tdk-lambda.com/patents
Refer to www.emea.tdk-lambda.com for installation manual.

GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use..... :	SMPS for building-in within end ME Equipment.
Device type (component/sub-assembly/ equipment/ system):	Component level SMPS unit
Intended use (Including type of patient, application location) :	EUT is intended to provide power to medical devices with isolation grade MOPP.
Mode of operation..... :	Continuous
Supply connection	SMPS for building-in not directly connected to the mains.
Accessories and detachable parts included .....:	No accessories and detachable parts included.
Other options include..... :	No other options included.
Testing	
Date of receipt of test item(s) ..... :	2014-06-02, 2014-09-16, 2014-10-03, 2014-10-08, 2014-10-17, 2014-10-20
Dates tests performed ..... :	From 2014-06-20 to 2014-10-22
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 + A1. 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) TDK-Lambda UK Limited** **Kingsley Avenue, Ilfracombe, Devon EX34 8ES,** **United Kingdom** **2) Panyu Trio Microtronic Co., Ltd** **Shiji Industrial Estate, Dongyong, Nansha,** **Guangzhou Guangdong,** **China**

General product information:

The power supply is an open frame switch mode power supply for building-in.

The power supply can be used as Class I or Class II construction.

- **For Class I construction, the SMPS need to be reliably earthed and professionally installed and fixed with metal screws.**
- **For Class II construction no earthing connection is required. The SMPS need to be fixed so, that it is insulated from any unearthed accessible conductive part by at least 2 x MOPP for a working voltage of 240 Vrms (e.g. fixed to metal enclosure by means of plastic spacers and plastic screws).**

The power supply provides internally two fuses, one in line and one in neutral.

The power supply may be either forced air or convection cooled. Due to the fact, that air flow for cooling depends on end product use, only convection cooling was considered during temperature measurement.

Therefore, the following temperatures within end ME Equipment use shall not be exceeded:

Circuit Ref.	Description	Max. Temperature (°C)
L1	Common Mode Choke	155
C6, C7, C8	Electrolytic Capacitors	105
C5	Electrolytic Capacitors	105
C1	X Capacitor	100
C2, C3, C4, C10, C11	Y Capacitors	125
TX1	Transformer Winding	155
XU2, XU4	Opto-Coupler	100
J1	Input Connector	85
J2	Output Connector	85

Model Differences:

All models provide different transformer construction. The secondary output windings have different number of turns to get different secondary output voltages.

12V and 15V models have an additional secondary winding (W4). This winding is not used for the other models. Winding W4 utilises is made of triple insulated wire, which provides 2 x MOOP between the output contacts. Therefore, no short or overload was applied directly on the output contacts.

2 different PCB layouts are used: the 12V & 15V models have the same PCB layout, and the 24V, 28V, 36V and 48V models have the same PCB layouts.

The units provide also differences in electrical scheme due to different output voltages:

- **12V & 15V models have different values of resistors XR20, XR21, XR35 and XR42**
- **24V, 28V, 36V and 48V models have different values of resistors XR20, XR21, XR5, XR41**

The following components are glued to prevent movement:

- **For 12V & 15V models: RT1, C5, C11, C7, C8, C9, C12, FE wire on PCB near C8, primary windings of transformer TX1 on PCB**
- **24V, 28V, 36V and 48V models: RT1, C5, C6, C7, C8, C11, C2, FE wire on PCB near C2/C11, primary windings of transformer TX1 on PCB**

Explanation of the test program:

a) Power supply unit was evaluated only for Means of Patient Protection (MOPP)

b) Secondary output circuit is separated from mains by reinforced insulation and rated SELV. The output does not provide hazard energy level.

c) In case the power supply is used as class I construction, the power supply shall be properly bonded to the main protective bonding termination in the end product. The earth leakage current is within the specified limits.

d) The transformers TX1 provides reinforced insulation und utilize a UL Insulation System (see appended table 8.10 for details).

e) The equipment has been evaluated for use in a Pollution Degree 2 and overvoltage category II environment and a maximum altitude of 5000m. See Insulation Diagram and Insulation Table

f) A suitable Electrical and Fire enclosure shall be provided in the end equipment.

g) The SMPS was evaluated for convection cooling for a maximum ambient of 50°C with the following output load condition. Additionally, from 85 Vac to 90 Vac input voltage, the output power is de-rated linearly from 80 W to 70 W.

Model	Output voltage (V⎓)	Output current (A)	Output power (W)
ZMS100-12	12	6,7	80,4
ZMS100-15	15	5,4	81
ZMS100-24	24	3,4	81,6
ZMS100-28	28	2,9	81,2
ZMS100-36	36	2,25	81
ZMS100-48	48	1,67	80,2

h) The SMPS was also evaluated for convection cooling for a maximum ambient up to 70°C with the output power (see table above) de-rated at 2,5% per °C from 50°C to 70°C ambient.

i) The power supply may be either forced air or convection cooled. Due to the fact, that air flow for cooling depends on end product use, only convection cooling was considered during temperature measurement.

Technical Considerations:

1. Scope of Power Supply evaluation defers the following clauses to be determined as part of the end product investigation:

- **Clause 7.5 (Safety Signs),**
- **Clause 7.9 (Accompanying Documents),**
- **Clause 9 (ME Hazard), except 9.1 and 9.3 are evaluated,**
- **Clause 10 (Radiation),**
- **Clause 14 (PEMS),**
- **Clause 16 (ME Systems)**
- **Risk Management was excluded from this investigation.**

2. Risk Controls/ Engineering Considerations for component power supply:

For use only in or with complete equipment where the acceptability of the combination is determined by the CB Testing Laboratory, when installed in an end-product, consideration must be given to the following:

• For Power Supplies with No RM: End product Risk Management Process to include consideration of requirements specific to the Power Supply.

• For Power Supplies with No RM: End product Risk Management Process to consider the need for simultaneous fault condition testing.

• For Power Supplies with No RM: End product Risk Management Process to consider the need for different orientations of installation during testing.

• For Power Supplies with No RM with Exposure Condition outside of Humidity Range: Power Supply tested in 21,3°C, 93%RH. End product Risk Management Process to determine risk acceptability criteria.

• For Power Supplies with No RM and Insulating Materials: End product to determine the acceptability of risk in conjunction to insulation to resistance to heat, moisture, and dielectric strength.

• For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the movement of components as part of the power supply.

• For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the movement of conductors as part of the power supply.

• For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the routing of wires away from moving parts and sharp edges as part of the power supply.

• For Power Supplies with No RM and Not tested with Test Corner: Temperature Test was conducted without Test Corner. End product to determine the acceptability of risk in conjunction to temperature testing without test corner as part of the power supply.

• For Power Supplies with No RM or Units without Cleaning/Disinfection Methods: End product to determine the acceptability of risk in conjunction to the Cleaning and Disinfection Methods as part of the power supply.

• For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the selection of components as it pertains to the intended use, essential performance, transport, storage conditions as part of the power supply

Approval within the end product:

- **Leakage current measurement should be verified with the unit built into the end product.**
- **EMC testing has to be performed together with the end medical product.**
- **Cleaning and disinfection shall be considered within end product investigation.**
- **Temperatures within end ME Equipment use shall not be exceeded.**