Test Report issued under the responsibility of:

TÜVRheinland®
Precisely Right.

IEC 60601-1
Medical electrical equipment
Part 1: General requirements for basic safety and essential performance

Report Reference No. ..... :	30992615.004	
Date of issue ..... :	March 13, 2011	.....
Total number of pages ..... :	31	.....
CB Testing Laboratory ..... :	TUV Rheinland of North America, Inc.	
Address ..... :	12 Commerce Road Newtown, CT 06470 USA	
Applicant's name..... :	TDK-Lambda Americas Inc.	
Address ..... :	3055 Del Sol Boulevard San Diego, CA 92154 USA	
Test specification:		
Standard..... :	IEC 60601-1: 2005	
Test procedure ..... :	CB	
Non-standard test method…….. :	N/A	
Test Report Form No. ..... :	IEC60601_1D	
Test Report Form Originator ..... :	Underwriters Laboratories Inc.	
Master TRF ..... :	Dated 2006-07	

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.

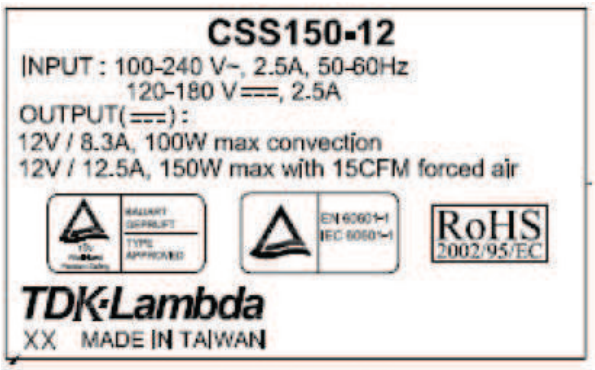
Test item description ..... :	Switch mode power supply
Trade Mark ..... :	TDK·Lambda
Manufacturer ..... :	TDK-Lambda Americas Inc. 3055 Del Sol Boulevard San Diego, CA 92154 USA
Model/Type reference ..... :	CSS150-12, CSS150-15, CSS150-24, CSS150-36, CSS150-48

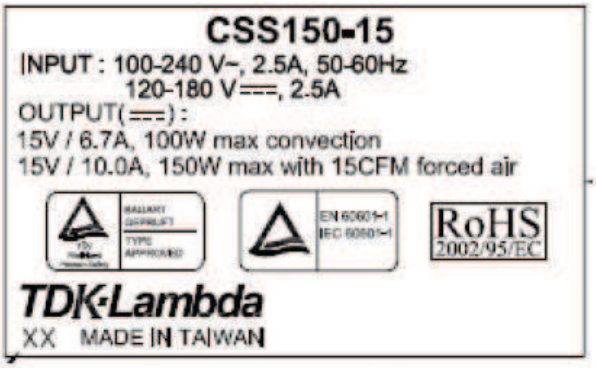
Ratings ..... :	CSS150-12: Input:100-240V, 2.5A, 50-60Hz / 120-180Vdc, 2.5A Output: 12Vdc, 8.3A, 100W max convection 12Vdc, 12.5A, 150W max w/ 15CFM forced air CSS150-15: Input:100-240V, 2.5A, 50-60Hz / 120-180Vdc, 2.5A Output: 15Vdc, 6.7A, 100W max convection 15Vdc, 10.0A, 150W max w/ 15CFM forced air CSS150-24: Input:100-240V, 2.5A, 50-60Hz / 120-180Vdc, 2.5A Output: 24Vdc, 4.2A, 100W max convection 24Vdc, 6.3A, 150W max w/ 15CFM forced air CSS150-36: Input:100-240V, 2.5A, 50-60Hz / 120-180Vdc, 2.5A Output: 36Vdc, 2.8A, 100W max convection 36Vdc, 4.2A, 150W max w/ 15CFM forced air CSS150-48: Input:100-240V, 2.5A, 50-60Hz / 120-180Vdc, 2.5A Output: 48Vdc, 2.1A, 100W max convection 48Vdc, 3.1A, 150W max w/ 15CFM forced air

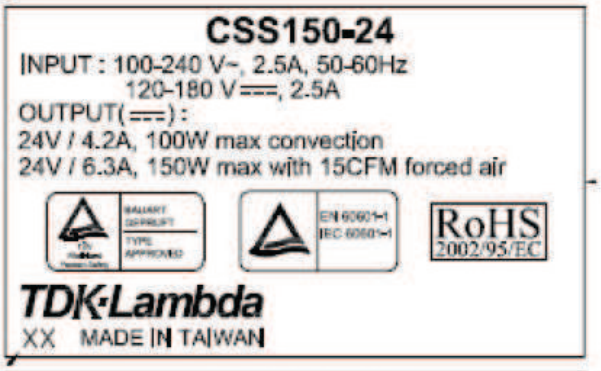
Testing procedure and testing location:	
☒ **CB Testing Laboratory**:	
Testing location/ address ..... :	TUV Rheinland of North America, Inc. 1279 Quarry Lane, Ste. A, Pleasanton, CA 94566
☐ **Associated CB Test Laboratory:**	
Testing location/ address ..... :	
Tested by (name + signature) ..... :	
Approved by (+ signature)..... :	
☐ Testing procedure: TMP	
Tested by (name + signature) ..... :	Ricardo Felix
Approved by (+ signature)..... :	Zhang Zhang
Testing location/ address ..... :	TDK-Lambda Americas Inc. 3055 Del Sol Boulevard San Diego, CA 92154 USA
☐ Testing procedure: WMT	
Tested by (name + signature) ..... :	
Witnessed by (+ signature) ..... :	
Approved by (+ signature)..... :	
Testing location/ address ..... :	
☐ Testing procedure: SMT	
Tested by (name + signature) ..... :	
Approved by (+ signature)..... :	
Supervised by (+ signature) ..... :	
Testing location/ address ..... :	
☐ Testing procedure: RMT	
Tested by (name + signature) ..... :	
Approved by (+ signature)..... :	
Supervised by (+ signature) ..... :	
Testing location/ address ..... :	

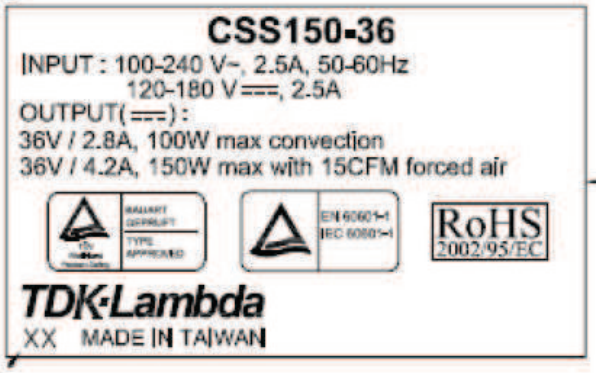
Summary of testing	
Tests performed (name of test and test clause):	**Testing location:**
DIELECTRIC VOLTAGE WITHSTAND: (IEC 60601-1, Sub-Clause 8.8.3 A) ABNORMAL OPERATION AND FAULT CONDITIONS: (IEC 60601-1, Clause 13.2)	TDK-Lambda Americas Inc. 3055 Del Sol Boulevard San Diego, CA 92154 USA
Summary of compliance with National Differences: CA, CH, SL, US	

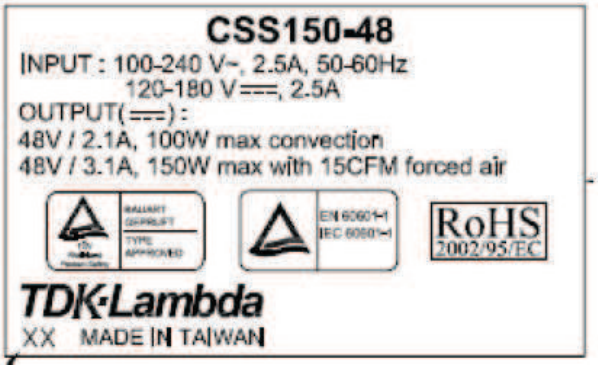
Copy of marking plate:











GENERAL INFORMATION	
Test item particulars (see also Clause 5):	
Classification of installation and use ..... :	For building-in
Device type ..... :	Power supply
Clinical application ..... :	Internal component
Mode of operation ..... :	continuous
Surface temperature of APPLIED PART ..... :	No applied parts
Supply connection ..... :	For building-in
Accessories and detachable parts included ..... :	None
Other options include ..... :	None
Testing	
Date of receipt of test item(s) ..... :	September 14, 2009 [30992615.001]
	March 9, 2012 [30992615.004]
Dates tests performed ..... :	September 14-16, 2009 [30992615.001]
	March 9-10, 2012 [30992615.004]
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 does not meet the requirement ..... :	Fail (F)
Abbreviations used in the report:	
- normal condition ..... :N.C.	- single fault condition ..... :S.F.C.
- operational insulation ..... :OP	- basic insulation ..... :BI
- basic insulation between parts of opposite polarity ..... :BOP	- supplementary insulation ..... :SI
- double insulation ..... :DI	- reinforced insulation ..... :RI

General remarks:

"(see Attachment #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.
Throughout this report a point is used as the decimal separator.
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.

General product information:

The equipment, model series as on the cover page, is a Class I switching type power supply intended for permanent installation into medical electrical apparatus.

The equipment shall be connected to the protective earth terminal of the final system. Compliance with the requirements of IEC/EN 60601-1-2 (EMC) shall be evaluated for the final system assembly.

All models have similar design and differ in construction (wiring turns and gauge) of separation transformer T1.

The dimensions of the double-layer PCB are 127mm by 76mm.

Report History:

30992615.004: Second amendment to report 30992615.001.

This report covers the addition of components to the Critical Component List. This test report is limited to the clauses affected. Changes to the report are in bold.

30992615.003: First amendment to report 30992615.001.

This report covers the correction of the factory address, addition of components to the Critical Component List and minor editorial corrections of the report. This test report is limited to the clauses affected. Changes to the report are in bold.

30992615.001: original report

Note: Gaps in the report numbering were reserved for TUV internal use, not related to the CB report.

Conditions of Acceptability:

1. The units are considered to operate under the conditions of:
   – Pollution Degree 2 environment
   – Equipment mobility: Component for building-in.
   – Class of equipment: Class I
2. Rated ambient is 50°C
3. Fire enclosure requirements must be addressed in the end-use product.
4. Re-evaluation of the heating, dielectric, and bonding tests need to conducted in the end-use product.
5. Short-circuit back-up protection in accordance with clause 2.7.3 shall be evaluated in end-use product.
6. Suitability of enclosure shall be provided in end product.
7. Power supply outputs are not investigated for limited power circuits.
8. Power supply insulation is investigated for isolation of HV to ground-stud chassis connections and SIP/SOP/SELV outputs only.
9. The power supply has not been evaluated for patient isolation.
10. The power supply must be bonded to protective earth in the end product at the point referenced by the functional ground symbol.