Test Report issued under the responsibility of:

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

Report Reference No. ..... :	E309264-D1015-1-CB
Date of issue ..... :	2015-07-17
Total number of pages ..... :	151
CB Testing Laboratory ..... :	UL Japan, Inc.
Address ..... :	4383-326 Asama-cho, Ise-shi, Mie, 516-0021, Japan
Applicant's name ..... :	TDK-LAMBDA CORP
Address ..... :	NAGAOKA TECHNICAL CENTER R&D DIV 2704-1 SETTAYA-MACHI NAGAOKA-SHI NIIGATA, 940-1195 JAPAN
Test specification:	
Standard ..... :	IEC 60601-1: 2005 + 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
Test Report Form Originator ..... :	UL(US)
Master TRF ..... :	2014-07

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.

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:	Medical Power Supply
Trade Mark:	Refer to Marking Label enclosure
Manufacturer:	TDK-LAMBDA CORP 2704-1 SETTAYA-MACHI NAGAOKA-SHI NIIGATA-KEN, 940-1195 JAPAN
Model/Type reference:	HWS30-**/ME Series
Ratings:	Input: 100-230 Vac, 50/60Hz, 0.9 A Outputs: See Enclosure "Miscellaneous"

Testing procedure and testing location:		
[X] CB Testing Laboratory:		
Testing location/ address:	UL Japan, Inc. 4383-326 Asama-cho, Ise-shi, Mie, 516-0021, Japan	
[ ] Associated CB Testing Laboratory:		
Testing location/ address:		
Tested by (name + signature):	Toshinori Mori	
Approved by (name + signature):	Tsutomu Abe	
[ ] 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): Refer to Appendix A of this report. All attachments are included within this report.
Summary of testing
Tests performed (name of test and test clause): Testing location: *Refer to the Test List in Appendix B of this report if testing was performed as part of this evaluation.*
Summary of compliance with National Differences List of countries addressed: Austria, USA, Canada, United Kingdom, Sweden

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.

Refer to the enclosure(s) titled Marking Plate in the Enclosures section in Appendix A of this report for a copy.

GENERAL INFORMATION	
Test item particulars:	
Classification of Installation and Use:	Built-in
Device Type:	Component
Intended Use Statement:	To supply regulated power, no patient connection
Mode of Operation:	Continuous
Supply Connection:	None
Accessories and detachable parts included:	None
Other Options Include:	None
Testing	
Date of receipt of test item(s) .....:	2015-05-28
Dates tests performed .....:	2015-06-09 to 2015-06-11
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
- 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 point is used as the decimal separator.	
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
When differences exist; they shall be identified in the General product information section.	

Name and address of factory (ies) .....:	TDK-LAMBDA CORP 2704-1 SETTAYA-MACHI NAGAOKA-SHI NIIGATA-KEN, 940-1195 JAPAN WUXI TDK-LAMBDA ELECTRONICS CO LTD NO 6 XING CHUANG ER LU WUXI SINGAPORE INDUSTRIAL PARK WUXI JIANGSU, 214028 P. R. CHINA TDK-LAMBDA (MALAYSIA) SDN BHD PLO33 KAWASAN PERINDUSTRIAN SENAI 81400 SENAI JOHOR MALAYSIA TDK-LAMBDA (MALAYSIA) SDN BHD LOT 2 & 3, BATU 9 3/4 KAWASAN PERINDUSTRIAN BANDAR BARU JAYA GADING 26070 KUANTAN MALAYSIA SENDAN ELECTRONICS MFG CO LTD 440-GOKA SHOGAWA-MACHI TONAMI-SHI TOYAMA-KEN 932-0313 JAPAN

GENERAL PRODUCT INFORMATION:

Report Summary

All applicable tests according to the referenced standard(s) have been carried out.

Refer to the Report Modifications page for any modifications made to this report.

Product Description

The HWS30-**/ME Series consists of open framed switch-mode power supplies providing 1MOOP between input and chassis and 2MOOP between input and output.

Model Differences

The power supplies are nearly identical in mechanical and electrical design especially with respect to the primary input. The electrical differences mainly occur with regards to the transformer and some secondary components. Detailed list of model differences is included in the Enclosure "Miscellaneous" of this report, while transformer specifications may be found attached to the Enclosure "Diagrams".

Additional Information

The product has been previously evaluated by UL according to CB scheme to IEC 60601-1:2005 + CORR.1: 2006 + CORR.2: 2007, CB Test Report Ref. No. E309264-A18-CB-1, Correction 1, Correction 2 and Amendment 1. Tests conducted per mentioned above edition of the standard were reviewed and considered representative of the corresponding tests required by IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 as follows.

4.11 Power Input

8.5.4 Working Voltage Measurements
8.6.4a Impedance and Current Carrying Capability
8.8.4.1 Ball Pressure
11 Temperature
13 Abnormal Operation Testing
15.5.1.2 Transformer Short Circuit
15.5.1.3 Transformer Overload

Additional tests were conducted for verification, and to fill a gap between 3rd edition without Amendment 1 and 3rd edition with Amendment 1.

CB Test certificates for components are included in Licenses Enclosure. In accordance with the current rules of CB Scheme, CB Test certificate is effective for 3 years. Recognizing NCB may challenge the CBTC when certificates are more than 3 years.

When submitting this Test Report to other Certification Body, the manufacturer is responsible for providing any additional information that the Body may need in order to issue its Mark, including testing for compliance with the applicable collateral standards.

Technical Considerations

- The product was investigated to the following additional standards:
  EN 60601-1:2006/A1:2013, ANSI/AAMI ES60601-1:2005/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14, BS EN 60601:2006 A1, SS-EN 60601-1:2006+A11:2011+A1:2013+AC1:2014+A12:2014
  Additional: N/A
- The following additional investigations were conducted: N/A
- The product was not investigated to the following standards or clauses: Biocompatibility (ISO 10993-1), Clause 14, Programmable Electronic Systems, Electromagnetic Compatibility (IEC 60601-1-2), Risk Management
- The following accessories were investigated for use with the product: N/A
- No Other Considerations.

Engineering Conditions of Acceptability

When installed in an end-product, consideration must be given to the following:

Considerations to the applied parts requirement, to be conducted as end-product.

Consideration should be given to measuring the temperature on power electronic components and transformer windings when the power supply is installed in the end-use equipment. The end-use product shall ensure that the power supply is used within its ratings.

The output circuits have not been evaluated for direct patient connection (Type B, BF or CF)

The input/output terminals are not acceptable for field connections, they are only intended for factory wiring inside the end-use product.

The component shall be installed in compliance with the enclosure, mounting, marking, spacing, and separation requirements of the end use application.

Power supply provides the following MOOP (means of operator protection): 2MOOP based upon a working voltage 250 Vrms, 386 Vpk between Primary to Secondary, 1MOOP based upon a working voltage 250 Vrms, 386 Vpk between Primary and Earth

Temperature, Leakage Current, Protective Earthing, Dielectric Voltage Withstand, and Interruption of the

Power Supply tests should be considered as part of the end product evaluation.

Proper bonding to the end-product main protective earthing termination is required.

The product was tested for use at the maximum ambient temperature (Tma) permitted by the manufacturer's specification of 50°C with 100% load, 60°C with 60% load, and 70°C with 20% load. See Enclosure "02 Derating curve" for additional details regarding output derating depends on the product orientation.

Transformer (T1) employ a Class B (130°C) insulation system.

The products were tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.

Additional fusing may be required in the end product to meet the requirement of Cl. 8.11.5, Mains fuses and Over Current Release. The product is only provided and tested with a single fuse.

The end-product evaluation shall ensure that the requirements related to Accompanying Documents, Clause 7.9 are met.

The product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide: No

The Clearances have additionally been assessed for suitability up to 3000 m elevation.

The risk management requirements of the standard were not addressed.

The investigated Pollution Degree is : 2