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-D1008-1/A1/C0-CB
Date of issue ..... :	2015-07-17 (Original), 2016-04-01 (Amendment 1)
Total number of pages ..... :	173
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

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 Grade Power Supply
Trade Mark:	Refer to Marking Label enclosure
Manufacturer:	Same as Applicant
Model/Type reference:	HWS600-xx/ME(SC), Where xx represents the output voltage rating and can be one of the following: 5, 12, 15, 24, 48. SC is an optional suffix for the HWS600-24/ME only.
Ratings:	HWS600-xx/ME(SC): Class I, No Patient Applied Parts Input: 100 - 240 Vac, 50 / 60 Hz, 9.0 A HWS600-5/ME: Output: 5 Vdc (4 - 6 Vdc), 120 Adc HWS600-12/ME: Output: 12 Vdc (9.6 - 14.4 Vdc), 53 Adc HWS600-15/ME: Output: 15 Vdc (12 - 18 Vdc), 43 Adc HWS600-24/ME(SC): Output: 24 Vdc (19.2 - 28.8 Vdc), 27 Adc HWS600-48/ME: Output: 48 Vdc (38.4 - 52.8 Vdc), 13 Adc

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):	Atsushi Fuchita	
Approved by (name + signature):	Jun Orito	
[ ] 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 [X] The product fulfils the requirements of IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint).

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 (see also Clause 6):	
Classification of Installation and Use:	Built-in
Device type (component/sub-assembly/ equipment/ system):	Component
Intended use (Including type of patient, application location):	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) .....:	2015-05-13 (Original)
Dates tests performed .....:	2015-06-12 to 2015-06-15 (Original)
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 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 1010 HABUSHIN NANTO-SHI TOYAMA-KEN 939-1756 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 model HWS600-xx/ME(SC) family of Medical Grade Power Supplies are intended for building into endproduct installations.

The power supply features screw terminals for connection of input and output wiring, and an all metal enclosure which surrounds the componentry of the equipment. Two auxiliary connectors are also provided for voltage feedback and on/off control of the power supply. A cooling fan is provided and is mounted as part of the enclosure. All electronic components are mounted inside the enclosure on a Printed Circuit (Wire) Board.

The power supplies mounting and securement means are provided by four threaded openings in the left and underside of the equipment.

Means Of Operator Protection (MOOP) are provided. No Means Of Patient Protection (MOPP) are provided.

Model Differences

The HWS600-xx/ME(SC) family of Medical Grade Power Supplies are all identical in form and function except for the output rating and leakage current protection of the equipment.

As above, xx represents the output voltage rating and can be one of the following: 5, 12; 15; 24; 48.

SC is an optional suffix for the HWS600-24/ME only, and when present indicates that the equipment is fitted with a long life fan.

The rating information is presented at the front of this report. Copy of Marking Plate is representative of all models.

The output rating are as follows;
- HWS600-5/ME: Output: 5 Vdc (4 - 6 Vdc), 120 Adc
- HWS600-12/ME: Output: 12 Vdc (9.6 - 14.4 Vdc), 53 Adc
- HWS600-15/ME: Output: 15 Vdc (12 - 18 Vdc), 43 Adc
- HWS600-24/ME(SC): Output: 24 Vdc (19.2 - 28.8 Vdc), 27 Adc
- HWS600-48/ME: Output: 48 Vdc (38.4 - 52.8 Vdc), 13 Adc

Copy of Marking Plate is representative of all models.

Additional Information

These products have been previously evaluated to IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) as detailed in CBTR Ref. No E309264-A54-CB-1 and CB Test Certificate Ref No. US-19855-UL and evaluated to IEC 60601-1:1988+ A1:1991+ A2:1995 (2nd ed.), UL 60601-1: 1st ed., 2006-04-26 (includes National Differences for USA) and CAN/CSA-C22.2 No. 601.1-M90 (R2005) (includes National Differences for Canada) under Test Report No. E309264-A8 by UL, and also evaluated to IEC 60950-1:2005 under Test Report No. E122103- A38 by UL. All tests conducted per 2nd ed. of IEC 60601-1 and IEC 60950-1 were considered representative of the corresponding tests required by 3rd ed. of IEC 60601-1 as stated under Summary of Testing.

Based on the previously conducted testing and the review of product technical documentation including photos, schematics, wiring diagrams and similar, it has been determined that the product continues to comply with the standard.

All required tests were carried out under the original investigation.

The following test was conducted in this evaluation as the previously evaluated Test Report might have been insufficient.

- Cl. 5.7: Humidity Preconditioning
- Cl. 8.7.3 e): Non-frequency-weighted Leakage Current
- Cl. 8.8.3: Dielectric Voltage Withstand

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 (from country differences):

  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 standards: 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 (ISO14971)

- 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 connectors 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.

The unit provides the following MOOP (means of operator protection): 2 MOOP based upon a working voltage 364Vrms, 616Vpk between input circuit of isolation transformer (T21); 272Vrms, 632Vpk between input circuit of isolation transformer (T32); 250Vrms, 450Vpk between input circuit of isolation transformer (T33); and transformer output circuit. And the core of the transformer is treated as primary.

Isolation transformer T21 employs a Class A (105 degree C) insulation system.

Isolation transformer T32 employs a Class F (155 degree C) insulation system.

Isolation transformer T33 employs a Class A (105 degree C) insulation system.

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 submitted and tested for use at the manufacturer's recommended ambient temperature (Tmra) of 50°C.

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.

Due to insufficient creepage distance between L and N in the I/O Terminal connection area on PWB, the necessity of a short circuit simulation per Clause 8.9.2 a) needs to be considered in the end-use product.

The functional enclosure provided on some submodels has not been evaluated as a fire enclosure.

The investigated Pollution Degree is : 2

Report Modifications

Date Modified *(Year-Month-Day)*	Modifications Made (include Report Reference Number)	Modified By
2016-04-01	Amendment 1: (E309264-D1008-1/A1/C0-CB) This amendment 1 involves the following modifications. - Addition of alternate Inductors (L1, L2), TDK-Lambda Corp., A21004* (* is any letter A - Z or blank) - Deletion of alternate Capacitors (C3, C4, C10, C11, C14, C15, C33), Panasonic Corp., Type NS-A - Change of address of factory, SENDAN ELECTRONICS MFG CO LTD from 440-GOKA SHOGAWA-MACHI TONAMI-SHI TOYAMA-KEN 932-0313 JAPAN to 1010 HABUSHIN NANTO-SHI TOYAMA-KEN 939-1756 JAPAN - Change of address of factory, WUXI TDK-LAMBDA ELECTRONICS CO LTD from NO 6, XING CHUANG ER LU, WUXI SINGAPORE INDUSTRIAL PARK, WUXI JIANGSU 214028, P.R. CHINA to NO 6 XING CHUANG ER LU WUXI JIANGSU 214028 CHINA No tests were considered necessary due to the similarity to the previously evaluated model and as this modification would not give negative impact to product safety. This Test Report is only valid in conjunction with Test Report Ref. No. E309264-D1008-1-CB, Cert. No.US-25652-UL, issued at 2015-07-27.	Atsushi Fuchita