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.....:	**4787342534**
Date of issue .....:	**2016-03-03**
Total number of pages.....:	**12**
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

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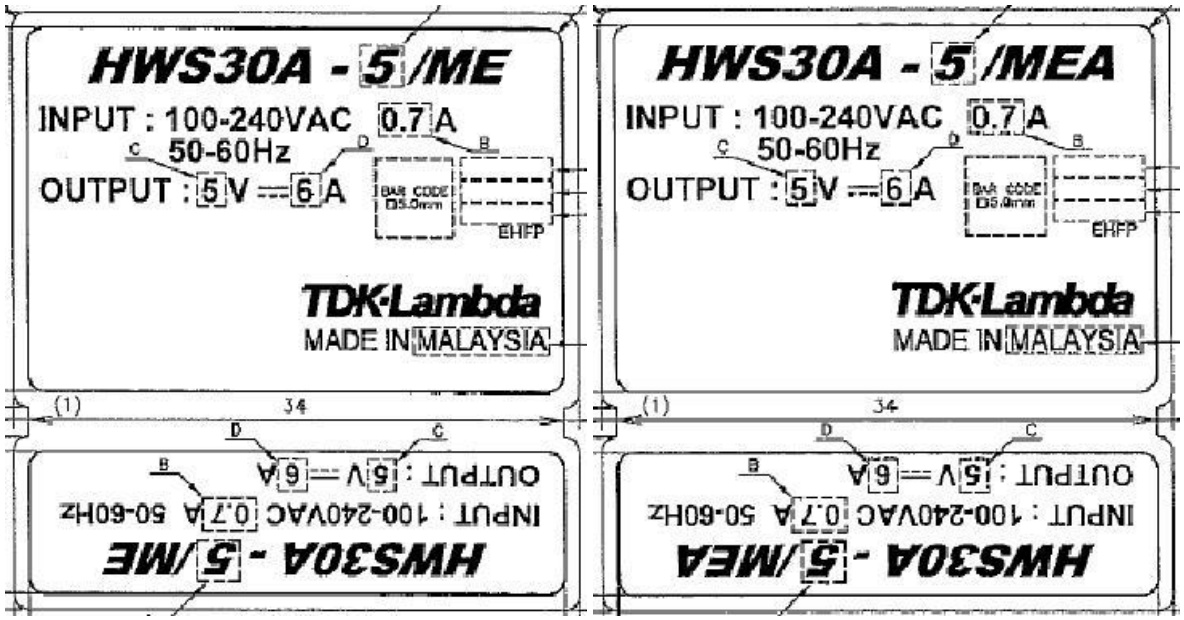
Test item description .....:	Medical Grade Power Supply
Trade Mark .....:	TDK·Lambda
Manufacturer.....:	TDK-LAMBDA CORP NAGAOKA TECHNICAL CENTER R&D DIV 2704-1 SETTAYA-MACHI NAGAOKA-SHI NIIGATA 940-1195 JAPAN
Model/Type reference.....:	HWS30A-xx/ME and HWS30A-xx/MEA Where xx represents the output voltage rating, and can be one of the following: 5, 12, 15, 24, or 48.
Ratings.....:	<Input> HWS30A-xx/ME, HWS30A-xx/MEA: 100 - 240 V ac, 50 - 60 Hz, 0.7 A <Output> (1) HWS30A-5/ME, HWS30A-5/MEA: 5 V ⎓, 6 A (2) HWS30A-12/ME, HWS30A-12/MEA: 12 V ⎓, 2.5 A (3) HWS30A-15/ME, HWS30A-15/MEA: 15 V ⎓, 2.0 A (4) HWS30A-24/ME, HWS30A-24/MEA: 24 V ⎓, 1.3 A (5) HWS30A-48/ME, HWS30A-48/MEA: 48 V ⎓, 0.65 A

Testing procedure and testing location:			
☒	**CB Testing Laboratory:**	UL Japan, Inc.	
Testing location/ address ..... :		4383-326 Asama-cho, Ise-shi, Mie, 516-0021, Japan	
☐	**Associated CB Testing Laboratory:**		
Testing location/ address ..... :			
Tested by (name + signature)..... :		Atsushi Fuchita	A. Fuchita
Approved by (name + signature) ..... :		Jun Orito	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): Enclosures (2 pages)
Summary of testing
Tests performed (name of test and test clause): **Testing location:** No tests were conducted.
Summary of compliance with National Differences List of countries addressed: AT, CA, GB, SE, US ☒ The product fulfils the requirements of IEC 60601-1: 2005 + CORR. 1: 2006 + CORR. 2: 2007 + AM1: 2012, ANSI/AAMI ES60601-1: 2005 + C1: 2009 + A2: 2010 + A1: 2012, CAN/CSA-C22.2 No. 60601-1: 14, EN60601-1: 2006 + CORR: 2010 + A11: 2011 + A1: 2013 + A12: 2014.

Copy of marking plate



GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use ..... :	Component for building-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	N/A (to be considered in end-use product)
Accessories and detachable parts included.....:	None
Other options include .....:	None
Testing	
Date of receipt of test item(s) .....:	N/A
Dates tests performed.....:	N/A
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.**	
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)..... :	WUXI TDK-LAMBDA ELECTRONICS CO LTD NO 6 XING CHUANG ER LU WUXI JIANGSU 214028 CHINA TDK-LAMBDA MALAYSIA SDN BHD PLO33 KAWASAN PERINDUSTRIAN SENAI 81400 SENAI MALAYSIA TDK-LAMBDA CORP 2704-1 SETTAYA-MACHI NAGAOKA-SHI NIIGATA-KEN 940-1195 JAPAN ALPS LOGISTICS FACILITIES CO LTD 593-1 NISHI-OHASHI TSUKUBA-SHI IBARAKI-KEN 305-0831 JAPAN SENDAN ELECTRONICS MFG CO LTD 1010 HABUSHIN NANTO-SHI TOYAMA-KEN 939-1756 JAPAN TDK-LAMBDA MALAYSIA SDN BHD LOT 2 & 3, BATU 9 3/4 KAWASAN PERINDUSTRIAN BANDAR BARU JAYA GADING 26070 KUANTAN MALAYSIA

General product information:

Report Summary
The original report was modified on 2016-03-03 to include the following changes/additions:

- Addition of factory, TDK-LAMBDA MALAYSIA SDN BHD, LOT 2 & 3 BATU 9 3/4 KAWASAN PERINDUSTRIAN BANDAR BARU JAYA GADING 26070 KUANTAN MALAYSIA

See Enclosure-Miscellaneous ID 7-01 for Manufacturer`s Declaration.

No tests were considered necessary as this modification would not affect safety.

This Test Report is only valid in conjunction with Test Report Ref. No. 4786814702, Cert. No. US-25010-UL at 2015-04-16.

Product Description
The models HWS30A-xx/ME and HWS30A-xx/MEA of Medical Grade Power Supplies are intended for building into end-product installations.

The power supply feature is intended to connect to UL recognized terminal block (TB1) by screws for input and output wiring.

2 Means Of Operator Protection (MOOP) are provided between Primary and Secondary on Transformer (T1) and Optocouplers (PC101, PC102).

Model Differences
HWS30A-xx/ME series are identical to HWS30A-xx/MEA series except without metal cover.

Where xx denotes the output voltage ratings, 5, 12, 15, 24, or 48.

Output ratings:
Models HWS30A-5/ME and HWS30A-5/MEA: 4.0 - 6.0 V dc, max 6 A, max 30.0 W.
Models HWS30A-12/ME and HWS30A-12/MEA: 9.6 - 14.4 V dc, max 2.5 A, max 30.0 W.
Models HWS30A-15/ME and HWS30A-15/MEA: 12.0 - 18.0 V dc, max 2.0 A, max 30.0 W.
Models HWS30A-24/ME and HWS30A-24/MEA: 19.2 - 28.8 V dc, max 1.3 A, max 31.2 W.
Models HWS30A-48/ME and HWS30A-48/MEA: 38.4 - 52.8 V dc, max 0.65 A, max 31.2 W.

General product information (continued):

Additional Information

Operating Condition: Unit was continuously operated with rated output load. The combination of output derating and the equipment orientation is specified in Enclosure-Miscellaneous ID No. 7-05 "Output derating curve - for without cover (p.1), for with cover (p.2)".

This equipment has two types of PWB (Type PZA-082A and Type PZA-082C). Difference between them is overvoltage protection circuit only.

The product has been previously evaluated by UL according to CB Scheme to IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) under CB Test Report No. E309264-A56-CB-1, Amendment 1, Amendment 2 and Amendment 3. Test results were derived from the CB Test Reports. In addition, new factory, SENDAN ELECTRONICS MFG CO LTD was added.

Unless otherwise stated, all tests were conducted on Model HWS30A-xx under maximum normal load condition described in General Product Information at input voltage, 90-264 Vac.
Difference between Models HWS30A-xx and Models HWS150A-xx/ME was only capacitance of Y-Capacitor (C2, C3). Model HWS30A-xx: maximum 2200 pF, Model HWS30A-xx/ME: maximum 1500 pF. Voltage or Charge Limitation (clause 8.4.3) and Earth leakage current (clause 8.7) were also conducted on Model HWS30A-48/ME.

The similar products, HWS30A-xx have been previously evaluated by UL according to CB Scheme to IEC 60950-1: 2005 (2nd Edition); Am 1:2009 under CB Test Report No. E122103-A143-CB-1 and Amendment 1. Test results for Limitation of voltage (clause 8.4.2) and Maximum voltage, current and power/energy (clause 8.4.2) were derived from the CB test reports. Model difference between Model HWS30A-xx and Model HWS30A-xx/ME in this report was only capacitance of Y-Capacitor (C2, C3). Model HWS30A-xx: maximum 2200 pF, Model HWS30A-xx/ME: maximum 1500 pF.

Because Dielectric Voltage Withstand (8.8.3) for some insulation tapes and Ball Pressure for terminal block material (TB1) have been previously evaluated by UL according to CB Scheme to IEC 60950-1:2005 (2nd Edition); Am 1:2009 under CB Test Report No. E122103-A138-CB-1 and Amendment 1, the test results were derived from the CB test reports.

Technical Considerations

- The equipment was investigated to the following additional standards: IEC 60601-1: 2005 + CORR. 1: 2006 + CORR. 2: 2007 + AM1: 2012, ANSI/AAMI ES60601-1: 2005 + C1: 2009 + A2: 2010 + A1: 2012, CAN/CSA-C22.2 No. 60601-1: 14, EN60601-1: 2006 + CORR: 2010 + A11: 2011 + A1: 2013 + A12: 2014.
- The equipment was not investigated to the following standards or clauses: Electromagnetic Compatibility (IEC 60601-1-2), Clause 14 Programmable Electronic Systems, Biocompatibility (ISO 10993-1), Usability (IEC 60601-1-6), Risk Management (ISO 14971)
- The degree of protection against harmful ingress of water is: Ordinary, IPX0
- The mode of operation is: Continuous
- The equipment is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide: No

General product information (continued):

Engineering Conditions of Acceptability

When installed in end products, consideration must be given to the following:

- The equipment is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide: No
- The unit provides the following MOOP (means of operator protection): 2 MOOP based upon a working voltage 273 Vrms, 480 Vpk between input circuit of isolation transformer (T1) and transformer output circuit. The core of the transformer is treated as float.
- Isolation transformer T1 employs a Class F (155 °C) insulation system.
- The output circuit has not been evaluated for connection to applied parts. For end products intended to connect the output circuit to applied parts, suitable evaluation of the separation, leakage current, dielectric voltage withstand, and related requirements should be considered.
- This unit is a power supply intended for building in. Final installation should comply with the enclosure, mounting, marking, spacing, and separation requirements. In addition, Temperature, Leakage Current, Dielectric Voltage Withstand, and Interruption of the Power Supply tests should be considered as part of the end product evaluation.
- This power supply was tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.
- Secondary outputs are SELV and non-hazardous energy level for all models.
- The end-use product shall ensure that the power supply is used within its ratings.
- The input/output terminals are not intended for field connections, they are only intended for factory wiring inside the end-use product.
- This power supply has been evaluated as Class I, altitude up to 4000 m (based on 62 kPa), pollution degree 2, overvoltage category II, continuous operation, ordinary equipment, and has not been evaluated for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. Additional evaluation shall be considered if the power supply is intended to be classified as the other conditions.
- The equipment was submitted and tested for use at the manufacturer's recommended ambient temperature (Tmra). See Enclosure-Miscellaneous ID No. 7-05 "Output derating curve - for without cover (p.1), for with cover (p.2)" for additional details regarding output derating and the equipment orientation.
- The equipment incorporates a fuse with high-breaking capacity in the Line conductor only. Consideration shall be given in the end-use product regarding additional fuse having the same or better characteristics in order to comply with fusing requirements of Clause 8.11.5 of the Standard.
- Earth terminal provided on Terminal Block (TB1) has not been evaluated as protective earthing terminal. If the earth terminal is treated as protective earthing in the end product, Limited Short-Circuit Test per CSA C22.2 No.04 shall be conducted. This component is intended to be bonded to a protective earth of the end product via chassis. Protective bonding mark (60417-1-IEC-5017) is provided on terminal block, however, Limited Short-Circuit Test per CSA C22.2 No.04 has not been conducted.
- Risk management process has not been conducted in this evaluation. Risk management process shall be conducted in the end product, including the evaluation of requirements related to the power supply.
- Instructions for use shall be checked in the product.