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-D1027-1/A0/C0-UL
Date of issue.....:	2017-2-14
Total number of pages.....:	172
Testing Laboratory.....:	UL Japan, Inc.
Address.....:	4383-326 Asama-cho, Ise-shi, Mie, 516-0021, Japan
Applicant's name .....:	TDK-LAMBDA CORP NAGAOKA TECHNICAL CENTER R&D DIV
Address.....:	2704-1 SETTAYA-MACHI NAGAOKA-SHI NIIGATA 940-1195 JAPAN
Test specification:	
Standard .....:	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)
Test procedure.....:	UL Certification
Non-standard test method……..:	N/A
Test Report Form No.....:	IEC60601_1K

General disclaimer:

The test results presented in this report relate only to the object tested.

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Test item description:	Switching Power Supply
Trade Mark:	Trademark image(s): TDK·Lambda
Manufacturer:	Same as Applicant
Model/Type reference:	RWS1000B-12/ME, RWS1000B-15/ME, RWS1000B-24/ME, RWS1000B-36/ME, RWS1000B-48/ME, Maybe followed by suffix "abcd" (a is R, b is CO2, c is FO, d is RF; and "a", "b", "c" and "d" may be blank) (for details, see General Product Information)
Ratings:	Input: 100-240 Vac, 13.0 A, 50-60 Hz Output: - RWS1000B-12/ME: 12 Vdc, 84 A - RWS1000B-15/ME: 15 Vdc, 67 A - RWS1000B-24/ME: 24 Vdc, 42 A - RWS1000B-36/ME: 36 Vdc, 28 A - RWS1000B-48/ME: 48 Vdc, 21 A

Testing procedure and testing location:		
[X] UL/DAP Testing Laboratory:		
Testing location/ address:	UL Japan, Inc. 4383-326 Asama-cho, Ise-shi, Mie, 516-0021, Japan	
Tested by (name, function, signature):	Jun Orito, Project Handler	
Approved by (name, function, signature):	Katsuyuki Kusagawa, Reviewer	

[ ] Testing procedure: WMT:		
Testing location/ address:		
Tested by (name, function, signature):		
Witnessed by (name, function, signature):		
Approved by (name, function, 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 D of this report if testing was performed as part of this evaluation.

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 owners of 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:	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) .....:	2016-09-19 to 2017-01-13
Dates tests performed .....:	2016-11-21 to 2017-01-18
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:

Before starting to use the TRF please read carefully the 4 instructions pages at the end of the report on how to complete the new version “J” of TRF for IEC for 60601-1 3rd edition with Amendment 1.
"(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.

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 equipment under tests is component type power supply for built-in type, model RWS1000B series, and intended for use in end-product equipment used in a hospital or related health care facility.

This equipment provides One Means Of Patient Protection (1MOPP) between Primary/Secondary and GND, and Two Means Of Patient Protection (2MOPP) between Primary and Secondary.

Output:

- RWS1000B-12/ME: 12 Vdc (10.2 to 13.8 Vdc), maximum 84 A (maximum 1008 W),

- RWS1000B-15/ME: 15 Vdc (12.75 to 17.25 Vdc), maximum 67 A (maximum 1005 W),
- RWS1000B-24/ME: 24 Vdc (20.4 to 27.6 Vdc), maximum 42 A (maximum 1008 W),
- RWS1000B-36/ME: 36 Vdc (30.6 to 41.4 Vdc), maximum 28 A (maximum 1008 W),
- RWS1000B-48/ME: 48 Vdc (40.8 to 55.2 Vdc), maximum 21 A (maximum 1008 W)

Model Differences

All the models are identical except for model designation, output rating, T3 secondary windings and plates (material, thickness, turns), T3 internal construction (related to secondary windings and plates), and secondary components.

Options "abcd" are defined as below.

- a: R (control on/off to output),
- b: CO2 (thin coating (QMJU2) on both sides of printed wiring board to prevent unintentional objectives from adhering),
- c: FO (remote sensing, parallel operation, low output voltage alarm),
- d: RF (DC fan with opposite direction and air flow, and different derating curve),

In addition, there is “RFO” combination "R" and "FO".

All the combinations using the options above are available except for "R"+"RFO" and "FO" + "RFO".

For “FO” and “RFO” only, transformer (T1) is used.

Additional Information

There is one more factory for CB only as shown below.

ZHANGJIAGANG HUA YANG ELECTRONICS CO LTD
TONGXIN RD
ZHAOFENG ECONOMIC DEVELOPMENT ZONE
LEYU TOWN
ZHANGJIAGANG
JIANGSU 215622 CHINA

There are various conditions of output loads, and four patterns of installation conditions. For details, see Enclosure Miscellaneous-(01).

Operating Condition: Unit was continuously operated with the rated output loads, considering derating curve and installation conditions.

Option “R”, “CO2”, “FO”, and “RFO” would not give impact to product safety.

Option “RF” was applied for test in addition to a standard model.

The same model was evaluated in E122103-A209-CB-1 (2016-12-22) under IEC 60950-1: 2005 (Second Edition) + Am1: 2009 + Am2: 2013. The difference in the model spec of IEC 60950 and 60601 is the capacitance and type of capacitors (C3, 4, 5, 6, 15, 20, 60, 61, 51, and 52) with suffix “/ME” which indicates medical use, and noise filter coil (L1). For details, see Enclosure Miscellaneous-(04). The noise filter coil (L1) differs in turns of coil only, DN-DL3153 (22 turns) and DN-DL3503 (14 turns). Leakage current test was conducted with the maximum capacitance of those capacitors.

Some test results were derived from E122103-A209-CB-1 due to the equivalent requirements to IEC 60601-1. For details, see Appendix D and test tables.

Technical Considerations

- The product was investigated to the following additional standards (from country differences):

EN 60601-1:2006/A1:2013, KS C IEC 60601-1, ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(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:

- The following additional investigations were conducted: N/A
- The product was not investigated to the following standards or clauses: Electromagnetic Compatibility (IEC 60601-1-2), Clause 14 Programmable Electronic Systems, Biocompatibility (ISO 10993-1), Risk Management (ISO 14971)
- The following accessories were investigated for use with the product: N/A
- There is no speed control in cooling fans.
- For some of critical components, EN standards were used to verify the compliance. The EN standards were harmonized to IEC standard, and technically equivalent.
- CB Test certificates for components are included in Licenses Enclosure.
- 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.
- The maximum specified operational ambient temperature is 50 ℃ at 100 % load, and 60 ℃ at 60 %.
- The degree of protection against harmful ingress of water is ordinary, IPX0.
- The mode of operation is continuous.
- The product is not suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide.
- Voltage deviation is +/-10 %. 85 Vac (-15 %) was excluded from this evaluation by the applicant`s request.

Engineering Conditions of Acceptability

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

- Overcurrent protection in accordance with cl. 8.11.5 shall be prepared in the end product. Also, opposite polarities between live and neutral (1MOOP) shall be evaluated in the end product.

- Dielectric Strength Test in the end product is to be based upon the maximum working voltage of: For RWS1000B-12/ME, PRI-GND 240 Vrms, 408 Vpk, PRI-SEC 240 Vrms, 446 Vpk. For RWS1000B-15/ME, PRI-GND 240 Vrms, 400 Vpk, PRI-SEC 240 Vrms, 446 Vpk. For RWS1000B-24/ME, PRI-GND 240 Vrms, 398 Vpk, PRI-SEC 240 Vrms, 458 Vpk. For RWS1000B-36/ME, PRI-GND 240 Vrms, 404 Vpk, PRI-SEC 255 Vrms, 496 Vpk. For RWS1000B-48/ME, PRI-GND 240 Vrms, 422 Vpk, PRI-SEC 279 Vrms, 574 Vpk.

- The output circuits have not been evaluated for direct patient connection (Type B, BF or CF). Additional requirements may be required if used for connection to applied parts.

- The following end-product enclosures are required: Electrical, Fire, Mechanical.

- All secondary output circuits are non-hazardous voltage, but all at hazardous energy level (240 VA) in accordance with cl. 8.4.2 c).

- The maximum investigated branch circuit rating is 20 A. If used on a branch circuit greater than this, additional testing may be necessary.

- Consideration should be given to measuring the temperature on power electronic components and transformer windings when the equipment is used with the end product. The end product shall ensure that

the equipment is used within its ratings.

- Instructions for use shall be checked in the end product.

- The equipment has been evaluated for use under Pollution degree 2, and at altitude up to 4000 m.

- Temperature Test was conducted without test corner. The acceptability of risk in conjunction to temperature testing with test corner shall be considered in the end product.

- Proper bonding to protective earthing terminal of end product shall be provided.

- Input and output connectors are not intended for field-wiring connection. They are only intended for factory-wiring inside the end product.

- Final installation of this equipment should comply with the enclosure, mounting, marking, spacing and separation requirements. In addition, Temperature, Leakage Current, Dielectric Voltage Withstand and Interruption of this equipment tests should be considered as part of the end product evaluation.

- Risk Management Process in accordance with cl. 4.2 shall be evaluated in the end product.

- The equipment has been judged on the basis of the required creepage and clearance according to cl. 8.9 in IEC 60601-1 Edition 3.1 (2012) that covers the end application for which the component was designed.

- The equipment has been evaluated as a Class I, continuous operation, IPX0, and not been evaluated for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. Additional evaluations shall be considered if the equipment is intended for classifications other than these.

- The following magnetic devices (e.g. transformers or inductor) are provided with an OBJY2 insulation system with the indicated rating greater than Class A (105 ℃): T1 (Class B), T3 (Class F)