Test Report issued under the responsibility of:

TEST REPORT
IEC 60601-1
Part 1: General requirements for basic safety and essential performance

Report Number..... :	**E349607-D13-CB-2-Amendment1**
Date of issue..... :	**2017-07-25; 2019-01-14(A1)**
Total number of pages ..... :	**240**
Name of Testing Laboratory preparing the Report ..... :	UL-CCIC Company Limited Guangzhou Branch Electronic Building Parage Electronic Industrial Park No. 8 Nanyun Er Road, Guangzhou Science Park Guangzhou 510663, China
Applicant's name ..... :	TDK-LAMBDA UK LTD
Address..... :	KINGSLEY AVE ILFRACOMBE DEVON, EX34 8ES UNITED KINGDOM
Test specification:	
Standard ..... :	IEC 60601-1:2005 (Third Edition) + 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_PS
Test Report Form(s) Originator .... :	UL(US)
Master TRF ..... :	2014-09

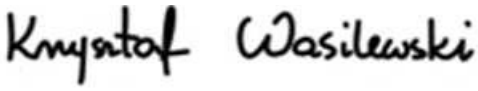
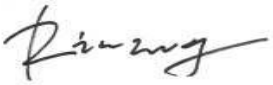
If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed.

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 Switch Mode Power Supply	
Trade Mark.....	TDK·Lambda	
Manufacturer.....	TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE DEVON EX34 8ES UNITED KINGDOM	
Model/Type reference.....	NV175 or NV-175 Series of power supply. (see Model Differences for details)	
Ratings.....	100-240Vac (Nominal), 45-63Hz, 3A (All AC models except as below) 88.9-240Vac (Nominal), 45-63Hz, 3A (Model NV1-1G000 only) (see Model Differences for details)	
Testing procedure and testing location:		
☐ **CB Testing Laboratory:**	UL-CCIC Company Limited Guangzhou Branch	
Testing location/ address	Electronic Building Parage Electronic Industrial Park No. 8 Nanyun Er Road, Guangzhou Science Park Guangzhou 510663, China	
☐ **Associated CB Testing Laboratory:**		
Testing location/ address		
Tested by (name + signature).		
Approved by (name + signature)		
☐ **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	TDK-Lambda UK Ltd, Kingsley Avenue, Ilfracombe, North Devon, EX34 8ES, United Kingdom	
Tested by (name + signature).	M.Carter, N.Marsh, Tester	
Witnessed by (name + signature)	Dennis Butcher, Witness	
Approved by (name + signature).....	Krzysztof Wasilewski, Project Reviewer	
Supervised by (name + signature)	Ricky Wang Project Handler	

List of Attachments (including a total number of pages in each attachment):

National differences (13)
Enclosures (105)

Summary of testing

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

Tests performed (name of test and test clause):

Excessive temperatures in ME equipment (11.1.1)
Electrical single fault condition (13.2.2)
Locking of moving parts (13.2.8)

Testing location:

TDK-Lambda UK Ltd
Kingsley Avenue
Ilfracombe
North Devon
EX34 8ES, United Kingdom

Summary of compliance with National Differences

List of countries addressed: AT, BE, BG, BY, CA, CH, CN, CZ, DE, DK, ES, EU, FI, FR, GB, GR, HU, IE, IL, IT, JP, KR, NL, NO, PL, PT, RO, SE, SG, SI, SK, UA, US

☒ The product fulfils the requirements of IEC 60601-1:2005 + CORR1 2006 + CORR2: 2007 + A1:2012, EN60601-1:2006 + A11:2011 + A1:2013 + A12:2014 (Medical electrical equipment Part 1: General requirements for basic safety and essential performance) CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes National Differences for Canada) ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes Deviations for United States)

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.

Please see enclosures 13-01 of this report for examples of marking plates.

GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use ..... :	For building in
Device type (component/sub-assembly/ equipment/ system):	Component Switched Mode Power Supply
Intended use (Including type of patient, application location) :	To provide DC power for electronic circuits within medical equipment.
Mode of operation ..... :	Continuous
Supply connection.....	Connection to the mains via host equipment
Accessories and detachable parts included ..... :	None
Other options include ..... :	None
Testing	
Date of receipt of test item(s)..... :	2018-08-07 to 2018-10-29
Dates tests performed..... :	2018-09-17 to 2018-10-29
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.

This Test Report Form is intended for the investigation of power supplies in accordance with IEC 60601-1:2005, 3rd edition + AM1. The Risk Management was excluded from the investigation; this shall be clearly identified in this report and on the accompanying CB Test Certificate.

Additional test data and/or information may be provided in the attachments to this report.

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) .....:	TDK-Lambda UK Ltd Kingsley Avenue Ilfracombe Devon EX34 8ES United Kingdom Panyu Trio Microtronic Co. Ltd Shiji Industrial Estate Dongyong Nansha Guangzhou, Guangdong, China

General product information:

Component Switch mode power supply NV175 or NV-175 series.

Report Summary

The test report should be read in conjunction with the original report number: E349607-D13-CB-2 issue on 2017-07-25, CB Cert No. DK-65814-UL, Issued on 2017-07-25.

Amendment 1 update is published to include the following changes/additions, This is technical amendment and that the amendment has to be read in conjunction with original report and previous amendments.:

1. Updates to the List of Critical Components,
2. Addition of alternate fan,
3. Addition of alternative fuse,
4. Updates to the enclosures as applicable.

Refer to "Summary of Testing" for details of testing carried out.

Product Description

Component Switch mode power supply NV175 or NV-175 series.

Model Differences

NV175 or NV-175 models as described below:

Units may be marked with a Product Code: K1x or Q1x where x may be any number of letters and/or numbers 0 to 9.

Unit Configuration (Description :) Code may be prefixed by NS # followed by / or - (where # may be any number of characters indicating non- safety related model differences).

Code may be followed by –SP to indicate “Special Price”.

Unit Configuration Code:

NVx-abcde-f-g-h-ijk

where:

x = 1 for 175
a = Number of Outputs : 1, 2, 3 or 4
b = Channel 1 Output Voltage†: 5, T, F, E or G
c = Channel 2 Output Voltage†: 1 , 2, 3, 5, 5L, 7, F or 0
d = Channel 3 Output Voltage†: 3L, 5L, 7, TL, FL, T, F, G followed by Y for negative output or 0
e = Channel 4 Output Voltage†: 3H, 5H, 7, T, F, TH, FH, 0H (fan only channel 4 output) followed by V for variable output followed by P for positive output or 0
f = Global Option : N for 5V version, N1 for 12V version, N2 for 13.5V version, N3 for 5V version with ATX compatibility, N4 for 12V version with ATX compatibility, N5 for 13.5V version with ATX, N6 for 12-13.5V version, N7 for 12-13.5V version with ATX or nothing for no Global Option present
g = U for U chassis, C for U chassis and cover, F for U chassis and cover with fan, I for U chassis and cover with fan and IEC inlet or nothing for Open Frame
h = Blank is the standard upright output connector, R is for the right angle output connector, H is for high altitude, HR is for high altitude with right angle output connector, M is for IEC60601-1, MR is for IEC60601-1 spacings with right angle connector
ijk = Three numbers from 0 to 9 which denotes various output voltages and currents within the specified ranges of each output for a particular unit or blank for standard output settings

† Table1: Output Voltage Cross Reference

Designation	Output Voltage
0	Omit output
A	1.5
1	1.8
B	2
2	2.7
3	3.3
5	5
7	7
T	12
F	15
E	18
G	24

Output channels and Global Options ratings are in accordance with the following table subject to variations and limitations of use below:

Output Channel	Designation	Vout	Adj. Range	Output Current
CH1	5	5	5 - 5.5	25A
	T	12	12 - 15.5	15A
	F	15	12 - 15.5	15A
	E	18	16 - 20	10A

	G	24	24 - 28.5	7.5A
CH2	1	1.8	0.9 - 3.8	15A
	2	2.7	2.5 - 3.8	15A
	3	3.3	2.5 - 3.8	15A
CH2 (CH1 12V)	5	5	3.3 - 5.5	10A
CH2 (CH1 15V)	5	5	3.3 - 5.5	10A
CH2 (CH1 24V)	5L	5	Fixed	2A
	5	5	3.3 - 5.5	8A
	7	7	5.5 - 8	5.5A
	F	15	12-15.5	6A
CH3	7	+/-7	7 - 8	5A
	T	+/-12	12 - 15	5A
	F	+/-15	12 - 15	5A
	G	+/-24	18 - 24.5	2.5A
	3L	+/-3.3	Fixed	2A
	5L	+/-5	Fixed	2A
	TL	+/-12	Fixed	2A
	FL	+/-15	Fixed	2A
CH4	3H	+/-3.3	Fixed	2A
	5H	+/-5	Fixed	2A
	7	+/-7	7 - 8	1A
	T	+/-12	Fixed	1A
	F	+/-15	Fixed	1A
	TH	+/-12	Fixed	2A
	FH	+/-15	Fixed	2A
	THV	+/-12	12 - 15	2A
	FHV	+/-15	12 - 15	2A
CH4 (fan output)	OH	-	-	-
Global Option	N	5	Fixed	2A
	N1	12	Fixed	1A
	N2	13.5	Fixed	1A
	N3	5(ATX)	Fixed	2A
	N4	12(ATX)	Fixed	1A
	N5	13.5(ATX)	Fixed	1A
	N6	12	12-13.5*	1A
	N7	12(ATX)	12-13.5*	1A

Channels 1 and 2 combined output currents must not exceed 25A
*Can only be set at the factory.

Variations and limitations of use:

All NV175 or NV-175 PSUs can output 180W except 5V channel 1 models which can output 175W. These power ratings are for channels 1 to 4. The global option output can be run in addition to the channel 1 to 4 maximum power outputs.

Units with channel 1 T and G outputs (no other channels fitted) have a peak power output of 200W including the global option with the following duty cycles:

In any 5 minutes 30% at 200W followed by 70% at 171W (average 180W)
In any 5 minutes 20% at 200W followed by 80% at 175W (average 180W)

Options -H and -HR meet spacings for 5000m.

Options -M and -MR meet IEC60601-1 Edition 2 Reinforced spacing’s with the following limitations (interpolated creepage spacings):

Channel 1 cannot be 5V model (T1 and T2 with foils)
Channel 2 cannot be fitted, except model K10142x where x may be any letter not affecting Safety.
Cannot be global option variants

Fan versions:

Channel 1 with G output, 25V maximum with 5V channel 2 maximum output current of 7A.
Channel 1 with G output, 25V maximum with 7V channel 2 maximum output current of 5.5A.
Channel 1 with G output, 5L channel 2 maximum output current 1.8A.
Channel 2 with T and F outputs, channel 2 maximum output current of 9A.
Channel 4 maximum output current of 1.5A

Model NV1-1G000 (with or without global option or -M/-MR option) may also be run with Channel 1 output voltage range 22.5V to 28V with maximum current of 7.5A and maximum power of 180W

Model NV1-1G000 (with or without -M option) may also be run at 80Vac to 264Vac input, output: 24V to 28V at 6.25A maximum current and 150W maximum power.

Model NV1-1G000-M operation to 4000m.

The products listed in the following table are typical examples:

Model	CH1	CH2	CH3	CH4	Global Option
NV1-453FF	5V/25A	3.3V/15A	15V/5A	15V/1A	-
NV1-4G5FFH-N3	24V/7.5A	5V/8A	15V/5A	15V/2A	5V/2A
NV1-350TT-N	5V/25A	-	12V/5A	12V/1A	5V/2A
NV1-453TT-N1	5V/25A	3.3V/15A	12V/5A	12V/1A	12V/1A
NV1-250T0-N2	5V/25A	-	12V/5A	-	13.5V/1A

Custom Models:

All ratings as per standard models unless otherwise stated.

Model: NS-LAM/NV1-453TTH-N2-H-C (K10035)
Rated to 4600m altitude
Input voltage range from 90Vac to 264Vac

Model: NS-LAMF/NV1-4G5TTH-F (K10066)
5L low current channel 2 fitted.
Channel 2 rated: 5V, 1.4A

Additional Information:
Cooling for units with customer supplied air (open frame, U and C options)

The following method must be used for determining the safe operation of PSUs.

The components listed in the following table must not exceed the temperatures given. To determine the component temperatures the heating tests must be conducted in accordance with the requirements of the standard in question. Consideration should also be given to the requirements of other safety standards. Test requirements include: PSU to be fitted in its end-use equipment and operated under the most adverse conditions permitted in the end-use equipment handbook/specification and which will result in the highest temperatures in the PSU. To determine the most adverse conditions consideration should be given to the end use equipment maximum operating ambient, the PSU loading and input voltage, ventilation, end use equipment orientation, the position of doors & covers, etc. Temperatures should be monitored using type K fine wire thermocouples (secured with cyanoacrylate adhesive, or similar) placed on the hottest part of the

component (out of any direct airflow) and the equipment should be run until all temperatures have stabilised.

Circuit Ref.	Description	Max. Temperature (°C)
L3, L7	Common mode choke winding	140
C1, C4	X capacitors	100
C6, C12	Capacitor	105
L2	Boost choke winding	130
C7	Electrolytic capacitor	70 (105)
T1, T2	Transformer winding	130
XU3	Control board optocoupler	100
TX701	Global option transformer	90
L5	Channel 1 Output choke	125
XL401	Channel 2 Output choke	125
XL601	5L channel 2 output choke	125
XU601	5L channel 2 IC	115
XL501 or XL601	Channel 3 and 4 output choke	125
IC1*	Channel 4 Voltage regulator	110
XQ406	Ch2 highside FET (SMA 2)	115
XV504	Ch3 highside FET (SMA 3)	115
XU601	Ch4 IC (SMA 4)	115
Various	All other electrolytic capacitors	90 (105)

* 1A channel 4 only

Higher temperatures limits (in brackets) may be used but product life may be reduced.

Technical Considerations

- The product was investigated to the following additional standards: EN60601-1:2006 + A1:2013 & EN60601-1:2006 + A11:2011 + A1:2013 + A12:2014 (Medical electrical equipment Part 1: General requirements for basic safety and essential performance), CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes National Differences for Canada), ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes Deviations for United States),

- 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)

- The degree of protection against harmful ingress of water is:: Ordinary

- The mode of operation is:: Continuous

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

- The IEC inlet and the fan assembly enclosure face must not be made accessible within the host equipment without further evaluation during installation.

- The IEC inlet and the fan assembly enclosure face must not be made accessible within the host

equipment without further evaluation during installation.

Engineering Conditions of Acceptability

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

- Insulation (Separation) between primary - secondary output circuits: 2 MOPPs for the -M and -MR models and 2 MOOPs for all other models. ,
- Power Supply tested in 25°C, 95%RH. End product Risk Management Process to determine risk acceptability criteria.
- The output circuits have not been evaluated for direct patient connection (Type B, BF or CF).
- End product Risk Management Process to include consideration of requirements specific to the Power Supply.
- End product to determine the acceptability of risk in conjunction to the use of Thermal Cut-off and Overcurrent releases as part of the power supply.
- Insulation (Separation) between primary - earth: 1 MOPP (-M and -MR only) or 1 MOOP.
- The power supplies have been assessed as component parts. It is the installer's responsibility to ensure that the final installation is in accordance with the NV175, NV-175 Handbook and that it is in compliance with IEC60601-1 & EN60601-1.
- Except for permanently installed equipment, the overall equipment in which these products are installed must be fitted with double pole fusing as detailed in the special instructions section of the NV175 handbook.
- This product range is available as a forced air-cooled version with a 3 pin input connector (Molex type) or an IEC60320 Inlet. It is also available as a customer air-cooled version where the end cap is not fitted and the customer must provide airflow and measure appropriate temperatures of components within the product. There are three versions of customer airflow, these being, Open frame, fitted with a "U" chassis, fitted with a "U" chassis and cover.
- Although the standard only requires testing for a 40°C ambient temperature the equipment has been rated and therefore tested for an operation at 50°C ambient temperature.
- A suitable fire and electrical enclosure must be provided by the end product.
- Connection to the protective conductor terminal within the end product must be ensured.
- Overcurrent protection must be provided by the end equipment to the neutral supply connection.
- The end-product Electric Strength Test is to be based upon a maximum working voltage of: Primary-

SELV 2 MOPPs: 278 Vrms, 542 Vpk(-M and -MR only). Primary-SELV 2 MOOPs: 337 Vrms, 616 Vpk. , Primary-Earthed Dead Metal: 306 Vrms, 418 Vpk(-M and -MR only). Primary-Earthed Dead Metal: 337 Vrms, 608 Vpk.

- Multilayer PWB's accepted under CBTR Ref. No.: E349607-A23 dated 2014-07-31 and letter Report,Enclosure 8-05 of this report.