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.....:	**E349607 - D5**
Date of issue .....:	**2015-04-13**
Total number of pages.....:	**213**
CB Testing Laboratory.....:	**UL International Demko A/S**
Address .....:	**Borupvang 5A 2750 Ballerup, Denmark**
Applicant's name.....:	**TDK-Lambda UK LTD**
Address .....:	**Kingsley Avenue, Ilfracombe, North Devon, EX34 8ES, UNITED KINGDOM**
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

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 .....:	**Switch Mode Power Supply**
Trade Mark.....:	TDK·Lambda
Manufacturer.....:	**TDK-Lambda UK Ltd** **Kingsley Avenue** **Ilfracombe** **North Devon** **EX34 8ES, United Kingdom**
Model/Type reference.....:	NV300 or NV-300 (See model differences for details of models and nomenclature)
Ratings.....:	100-240Vac nom, 5A rms max, 45-63Hz.

Testing procedure and testing location:			
☐	**CB Testing Laboratory:**	UL International Demko A/S	
Testing location/ address ..... :		Borupvang 5A 2750 Ballerup, Denmark	
☐	**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)..... :	Mr N. S. Marsh, Mr S. Hirstwood	
Witnessed by (name + signature) ..... :		
Approved by (name + signature) ..... :	Mr K. P. Tizzard	
Supervised by (name + signature)..... :	Dennis Butcher	

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

Enclosures (16)

Summary of testing:

This report to include IEC60601-1 + A1:2012, is a re-issue of CBTR ref No: E349607-A32-CB-1, dated: 2012-08-07 including CB Test Certificate Ref. No. DK-27463-UL dated: 2012-08-07. 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. Only the tests listed below was deemed necessary, to include the following changes/additions.

Unless otherwise indicated, all tests were conducted at TDK-LAMBDA UK, LTD., KINGSLEY AVE, ILFRACOMBE, DEVON, EX34 8ES UNITED KINGDOM.

Tests performed (name of test and test clause): **Testing location:**

Power Input Test (4.11)
Humidity Preconditioning Treatment (5.7)
Working Voltage Measurement (8.5.4)
Earthing and Potential Equalization Test (8.6.4a)
Dielectric Voltage Withstand (8.8.3)
Temperature Test (11)
Abnormal Operation and Single Fault Conditions (13)
Transformer Overload and Short-Circuit Tests (15.5.1)
Transformer Dielectric Voltage Withstand (15.5.2)

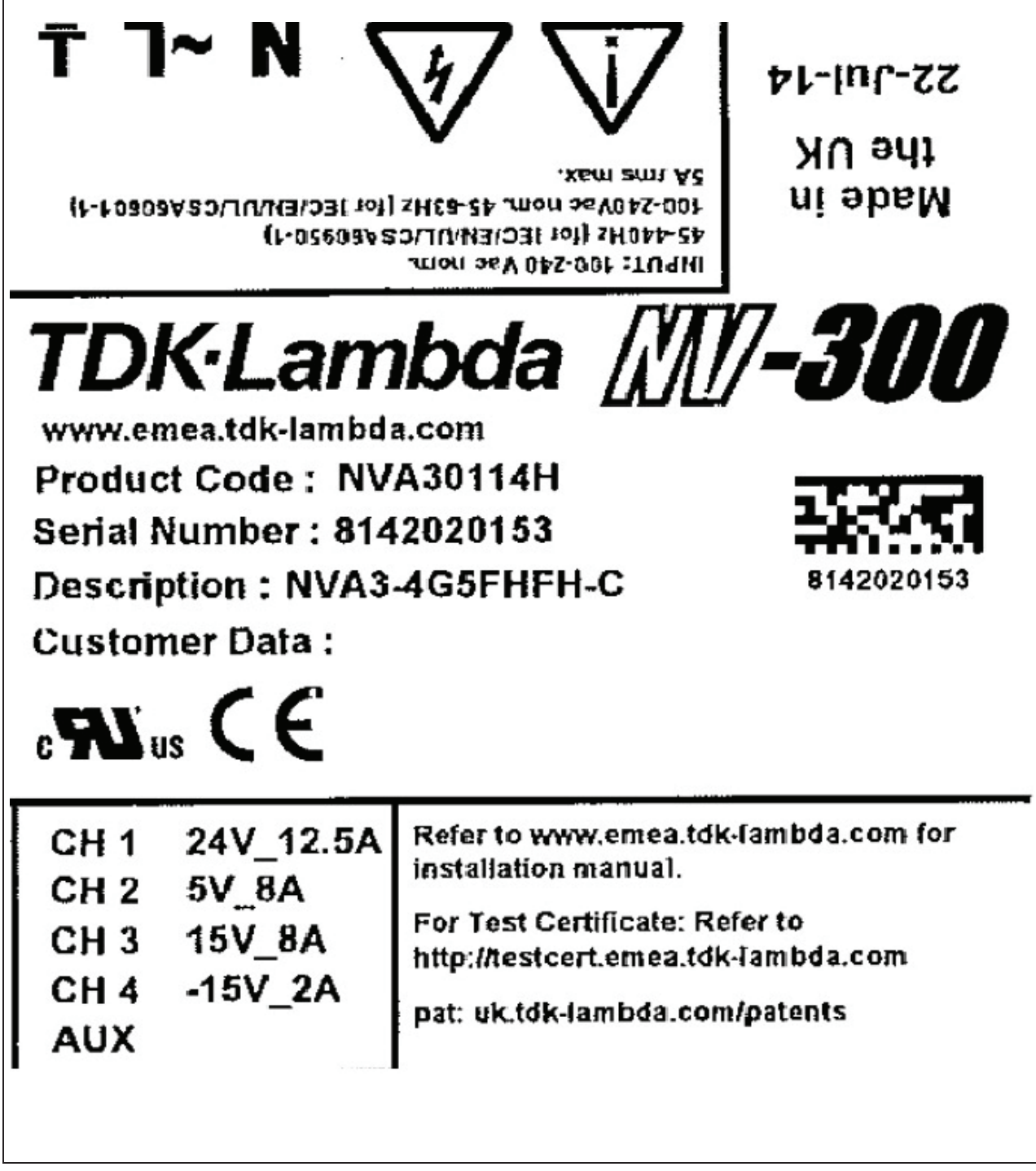
Summary of compliance with National Differences

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, SI, SK, UA, US

☒ The product fulfils the requirements of IEC 60601-1:2005 + A1:2012. EN60601-1:2006: + A1:2013. CAN/CSA-C22.2 No. 60601 (2008), ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10).

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.



GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use ..... :	For building into host equipment
Device type (component/sub-assembly/ equipment/ system):	Component
Intended use (Including type of patient, application location) :	To provide DC power for electronic circuits with in medical equipment
Mode of operation .....:	Continuous
Supply connection	For building into host equipment
Accessories and detachable parts included.....:	None
Other options include .....:	None
Testing	
Date of receipt of test item(s) .....:	2014-08-04 to 2014-10-14
Dates tests performed .....:	2014-08-04 to 2014-10-14
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 factories ..... :	
Factory ID: (478831-002)	**TDK-Lambda UK Ltd** **Kingsley Avenue** **Ilfracombe** **Devon** **EX34 8ES** **UK**
Factory ID: (477652-002)	**Panyu Trio Microtronic Co. Ltd** **Shiji Industrial Estate** **Dongyong** **Nansha** **Guangzhou, Guangdong,** **China**

General product information:

Report Summary

This report, to include IEC60601-1-1 amendment 1: 2013, is a re-issue of CBTR ref No: E349607-A32-CB-1, dated: 2012-08-07 including CB Test Certificate Ref. No. DK-27463-UL dated: 2012-08-07. 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.
Only the tests listed below were deemed necessary, to include the following changes/additions:

F2, alternative fuse testing (not mains input fuse)

Added Panyu Trio Microtronic Co. Ltd to the Factories list.

Re-assessed for hazardous energy outputs.

Assessed for 4000 meters

Assessed for MOPPs from Input to Earth

Updated handbook

Addition/deletion of multilayer PWBs to critical component list

Correction/addition to the critical component list

Updated licenses

Updated drawings

Tests deemed necessary during the current evaluation:

Working voltage/power measurement (8.4.2)
Dielectric Voltage Withstand (8.8.3)
Abnormal Operation and Single Fault Conditions (13)

Product Description

NV300 and NV-300 series. Switch mode power supplies for building in to end equipment.

Model Differences

NV300 or NV-300 models as described below:
Unit Configuration Code:

NVx-abcde-f-g-ijk
(may be prefixed by NS # followed by / or- where # may be any characters indicating non safety related model differences)

where:
x = A3 for 300 or -300
a = Number of Outputs : 1, 2, 3 or 4

b = Channel 1 Output Voltage†: 5, T or G
c = Channel 2 Output Voltage†: 1, 2, 2H 3, 3H, 5, 5H, T, F or 0
d = Channel 3 Output Voltage†: T, F, TH, FH, G or 0
e = Channel 4 Output Voltage†: 3H, 5H, T, F, TH, FH, 0H (fan only channel 4 output) followed by P for positive output or 0
f = Global Option : N3 for 5V version with ATX compatibility, N4 for 12V version with ATX, N5 for 13.5V version ATX compatibility 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
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

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
G	24

All channels are adjustable except for Channel 4 and Global Options in accordance with the following table:

O/P Channel	Designation	Vout (V)	Range (V)	I out (A)	Max Power (W)
CH1	5	5	5 - 5.5	40A	200
	T	12	12 - 13.2	25A	300
	G	24	24 - 28.5	12.5A	300
CH2 (CH1 5V)	1	1.8	0.9 - 2.5	15A	37.5
	2	2.7	2.5 - 3.8	15A	50
	2H	2.7	2.5 - 3.8	24A	80
	3	3.3	2.5 - 3.8	15A	50
	3H	3.3	2.5 - 3.8	24A	80
CH2 (CH1 12V)	5	5	3.3 - 5.5	10A	50
	5H	5	3.3 - 5.5	16A	80
CH2 (CH1 24V)	5	5	5 - 5.5	8A	40
	5H	5	5 - 5.5	12.5A	62.5
	T	12	12 - 15.5	10A	150
	F	15	12 - 15.5	10A	150
CH3	T	12	12 - 15	5A	60
	F	15	12 - 15	5A	60
	TH	12	12 - 15	8A	96
	FH	15	12 - 15	8A	96
	G	24	18 - 24.5	2.5A	60
CH4	3H	+/-3.3	Fixed	2A	6.6
	5H	+/-5	Fixed	2A	10
	T	+/-12	Fixed	1A	12
	F	+/-15	Fixed	1A	15
	TH	+/-12	Fixed	2A	24

	FH	+/-15	Fixed	2A	30
CH4 (fan output)	OH	-	-	-	-
Global Option	N3	5 (ATX)	Fixed	2A	10
	N4	12-13.5* (ATX)	Fixed	1A	12-13.5
	N5	12-13.5* (ATX)	Fixed	1A	12-13.5

*12-13.5 is the range. Nomenclature kept for legacy purposes.

Variations and limitations of use:
Maximum 300W power output. With 180Vac and greater input voltage, output power 300W plus global option (max 313.5W)
Channels 1 and 2 combined output currents must not exceed 40A.
Channel 1 with G output, 25V max with 5V channel 2 fitted.

Additional variations and limitations of use for fan version with 5V channel 1:
Output power de-rated 3W per volt from 100Vac to 90Vac (at 90Vac input, 270W output)
Unit with global option, high current channel 2 de-rated to 21A
Unit without global option, high current channel 2 de-rated to 19A
Unit without global option, low current channel 2 de-rated to 13A

Additional variations and limitations of use for all fan version:
Channel 4 3H, 5H, TH and FH max output current 1.5A.
The products listed in the following table are typical examples:

Model	CH1	CH2	CH3	CH4	Global Option
NVA3-453FFH	5V/40A	3.3V/15A	15V/5A	-15V/2A	-
NV3A-453HFHFH-N3	5V/40A	3.3V/24A	15V/8A	-15V/2A	5V/2A
NV3A-4GFGT-N5	24V/12.5A	15V/10A	24V/2.5A	-12V/1A	13.5V/1A

Output Limitations

All outputs have functional spacings to earth, and due consideration must be given to this in the end product design.
Adjusting output voltage beyond the stated range may cause overvoltage protection (OVP) to operate. To reset for normal operation simply adjust the potentiometer to reduce the output voltage to within its range or cycle the input off then on if the unit has latched off after adjusting the potentiometer.
Seriesing of outputs is not allowed.
Products may additionally be marked with Product Code NVA3x or Y3x where x may be up to any six letters and/or numbers 0 to 9 indicating non-safety related model differences.

Technical Considerations

- The product was investigated to the following additional standards:: IEC 60601-1:2005 + CORR1 2006 + CORR2: 2007 , EN 60601-1:2006 + CORR: 2010 (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 following accessories were investigated for use with the product:: None
- The mode of operation is:: Continuous
- The product is suitable for use in the presence of a flammable anesthetics 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.
- These products have been assessed for class 1, pollution degree 2, material group IIIb, overvoltage category II.
- Risk management has not been applied to these products
- The product is Classified only to the following hazards: Casualty, Fire, Shock.
- Classification of installation and use: Building-in.
- Multi-layer PWB's accepted under CBTR Ref. No. E349607-A23 dated 2014-07-31 and letter report, enclosure 8-05 of this report.

Engineering Conditions of Acceptability

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

- The insulation (separation) for these products is Basic insulation (1MOPP) between primary circuits and earth and Reinforced insulation (2 MOOPS) between primary and secondary circuits.
- The power supplies have been assessed as component parts of a host equipment. It is the installers responsibility to ensure that the final installation is in accordance with the NV300 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 NV300 handbook.
- This product range is available as 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
- The product was submitted and tested for use at a manufacturer's recommended ambient temperature (Tmra) of 50°C at Full Load and 65°C at Reduced Load.
- 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 following secondary output voltages are at hazardous energy levels: CH1.

- The following secondary voltages are at non-hazardous energy levels: CH2, CH3, CH4 and option.
- The following production line tests are conducted for this product: Electric strength and Earthing continuity.
- The maximum investigated branch circuit rating is 20A. If used on a branch circuit greater than this, , additional testing may be necessary
- The power supply terminals and/or connectors are not investigated for field wiring.
- The end product electric strength test is to be based upon a maximum working voltage of Primary to Secondary;422Vrms, 676Vpk. Primary to earth ;391Vrms, 426Vpk.
- Output circuits have not been evaluated for direct patient connection (Type B, BF, CF)
- Considerations to the applied parts requirement, to be conducted as end-product.
- End product Risk Management Process to include consideration of requirements specific to the Power Supply.
- Legibility of Marking to be considered / investigated in end use product. Durability test not conducted.
- PWB is rated 130°C.
- 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.
- product was assessed for an operational altitude of 4000M.