Test Report issued under the responsibility of:

TEST REPORT
IEC 60601-1
Medical Electrical Equipment
Part 1:General requirements for safety

Report Reference No ..... :	E349607-A6-CB-1
Date of issue ..... :	
Total number of pages ..... :	30
CB Testing Laboratory ..... :	UL International Polska Sp. z o.o.
Address ..... :	Aleja Krakowska 81, 05-090 Sekocin Nowy, Poland
Applicant's name ..... :	TDK-LAMBDA UK LTD
Address ..... :	KINGSLEY AVE ILFRACOMBE DEVON EX34 8ES UNITED KINGDOM
Test specification:	
Standard ..... :	IEC 60601-1:1988 + A1:1991 + A2:1995
Test procedure ..... :	CB Scheme
Non-standard test method ..... :	N/A
Test Report Form No. ..... :	IEC60601_1c/97-04
Test Report Form originator ..... :	UL LLC
Master TRF ..... :	dated 97-04

If this test Report 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 ..... :	Component Power Supply
Trade Mark ..... :	TDK-Lambda
Manufacturer ..... :	TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE DEVON EX34 8ES UNITED KINGDOM
Model/Type reference ..... :	NV350, NV-350, NF350 or NV3 Range (See enclosure 7-01 for details of model configurations)
Ratings ..... :	100-240Vac nominal (90-264V max. tolerance), 47-63Hz, 5.5A (See enclosure 7-01 for details of model ratings)

Testing procedure and testing location:		
[x]	**CB Testing Laboratory**	
	Testing location / address..... :	UL International Polska Sp. z o.o. Aleja Krakowska 81, 05-090 Sekocin Nowy, Poland
[ ]	**Associated CB Test Laboratory**	
	Testing location / address..... :	
	Tested by (name + signature) ..... :	Wojciech Czerniak (Project Handler) W. Czerniak
	Approved by (name + signature) ... :	Dennis Butcher (Reviewer)
[ ]	**Testing Procedure: TMP/CTF Stage 1**	
	Tested by (name + signature) ..... :	
	Approved by (+ signature) ..... :	
	Testing location / address..... :	
[ ]	**Testing Procedure: WMT/CTF Stage 2**	
	Tested by (name + signature) ..... :	
	Witnessed by (+ signature)..... :	
	Approved by (+ signature) ..... :	
	Testing location / address..... :	
[ ]	**Testing Procedure: SMT/CTF Stage 3 or 4**	
	Tested by (name + signature) ..... :	
	Approved by (+ signature) ..... :	
	Supervised by (+ signature) ..... :	
	Testing location / address..... :	
[ ]	**Testing Procedure: RMT**	
	Tested by (name + signature) ..... :	
	Approved by (+ signature) ..... :	
	Supervised by (+ signature) ..... :	
	Testing location / address..... :	

List of Attachments
National Differences (0 pages)
Enclosures (5 pages)
Summary of Testing:
No tests were conducted
Summary of Compliance with National Differences:

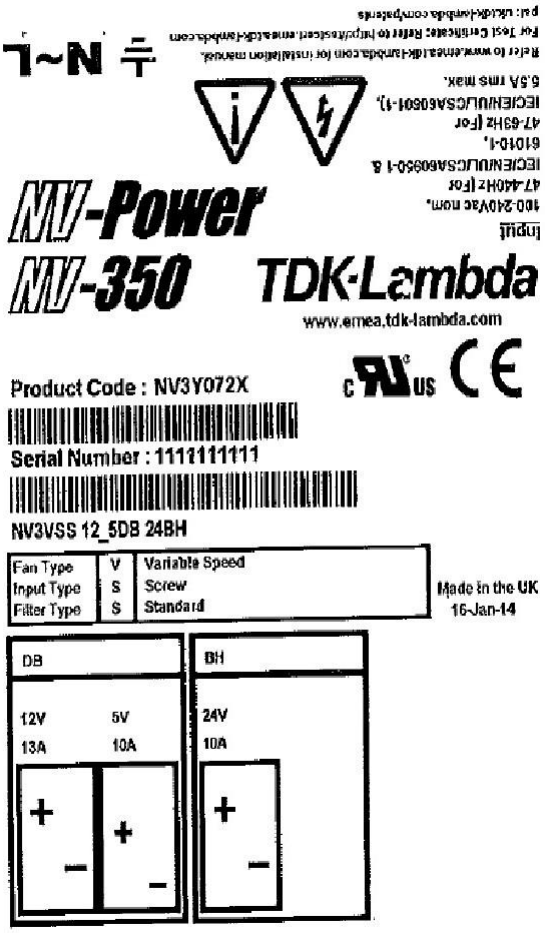
Countries outside the CB Scheme membership may also accept this report.

List of countries addressed: AT, AU, BE, BR, CA, CH, CZ, DE, DK, FI, FR, GB, GR, HU, IL, IN, IT, JP, KR, NL, NO, PL, RU, SE, SI, SK, UA, US

The product fulfills the requirements of: CAN/CSA-C22.2 No. 601.1-M90 (R2005) (includes National Differences for Canada)

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.



Test item particulars :				
Classification of installation and use .....:		Building into host equipment		
Supply connection .....:		Units configured with an appliance inlet are suitable for connection to the mains supply via an appliance coupler; Units configured with a mains terminal block to be supplied by the host equipment (upon installation)		
Accessories and detachable parts included in the evaluation .....:		None		
Options included .....:		None		
Possible test case verdicts:				
- test case does not apply to the test object .....:		N / A		
- test object does meet the requirement .....:		P(Pass)		
- test object does not meet the requirement .....:		F(Fail)		
Abbreviations used in the report:				
- normal condition .....:	N.C.	- single fault condition .....:	S.F.C.	
- operational insulation .....:	OP	- basic insulation .....:	BI	
- basic insulation between parts of opposite polarity:	BOP	- supplementary insulation .....:	SI	
- double insulation .....:	DI	- reinforced insulation .....:	RI	
Testing:				
Date(s) of receipt of test item .....:		N/A		
Date(s) of Performance of tests .....:		N/A		
General remarks: List of test equipment must be kept on file and be available for review. "(see Enclosure #)" refers to additional information appended to the report. "(see appended table)" refers to a table appended to the report. Throughout this report a point is used as the decimal separator.				
Manufacturer's Declaration per Sub Clause 4.2.5 of IECEE 02:				Yes
The application for obtaining a CB Test Certificate includes more than one factory 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 ..... When differences exist, they shall be identified in the General Product Information section.				
Name and address of Factory(ies):		TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE DEVON EX34 8ES UNITED KINGDOM PANYU TRIO MICROTRONIC CO LTD		

SHIJI INDUSTRIAL ESTATE
DONGYONG
NANSHA
GUANGZHOU GUANGDONG CHINA

GENERAL PRODUCT INFORMATION:

Report Summary

The original report was modified on 2017-05-22 to include the following changes/additions:
Alternate Y1 capacitors (C5, C6, C7) added to the critical components list. Their licences added to the enclosures.
CBTL changed to UL International Polska
Models updated.

Product Description

Component Power Supplies

This product range is available as a forced air cooled version (in-built fan) with screw terminal input connections or an IEC 60320 inlet. It is also available as customer air cooled versions (with and without a cover) where the end cap is not fitted and the customer must provide an air flow and measure appropriate temperatures of components within the product.

It should be noted that the power supplies have been assessed as a component part. It is the installers responsibility to ensure that the final installation is in accordance with the NV350 handbook and that it is in compliance with IEC60601-1.

Model Differences

Model NV3 is identical to the NV350 .
Models NV350FEP and NF3 are identical to the NF350.

All models use a common front end supply and fan assembly. The NV350FEP can only use the FE module due to the shorter case size whereas the NV350 can use any module with the exception of the FE module.

Cooling option U has a chassis, no fans and no cover and is therefore dependant on customer air. (Temperatures to be re-evaluated in the end equipment evaluation).

See enclosure 7-01 for details of models.

Additional Information

Project 4787707401 information:
This is Amendment 2 to the CB Test Report E349607-A6-CB-1 dated 2011-12-01 with CB Test Certificate DK-5219 and with Amendment 1 dated 2015-01-13 with CB Test Certificate DK-5219-A1-UL.

This Amendment is published due to changes provided in Report Summary.
No additional testing has been done.
This amendment shall be read in conjunction with Original Test Report and Test Certificate and with previous Amendment 1.

Technical Considerations

- The product was investigated to the following additional standards: IEC 60601-1, 2nd Edition: 1988, UL 60601-1, 1st Edition, 2006-04-26 (includes National Differences for USA), CAN/CSA-C22.2 No. 601.1-M90 (R2005) (includes National Differences for Canada)
- The product was not investigated to the following standards or clauses: Clause 36, Electromagnetic Compatibility (IEC 601-1-2), Clause 48, Biocompatibility (ISO 10993-1), Clause 52.1, Programmable Electronic Systems (IEC 601-1-4)
- The product is Classified only to the following hazards: Fire, Shock
- The degree of protection against harmful ingress of water is: IPX0
- The following accessories were investigated for use with the product: None
- The mode of operation is: Continuous
- Software is relied upon for meeting safety requirements related to mechanical, fire and shock: No
- The product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide: No
- Product evaluated for an operating temperature of 50°C (full load). --
- The product was investigated by UL for compliance with IEC60601-1. Some test results have been accepted based on the CB Test Report previously issued by BSI, CB Test Report Ref. No. 222/7225854, 222/4612938, 22/4827813 & 222/7050418, CB Test Certificate Ref. No. GB784W & GB668W/M2 as identified in this report --
- Multi-layer PWB's accepted under CBTR Ref. No. E349607-A23 dated 2014-07-31 and letter report, Enclosure 8-08 of this report --

Engineering Conditions of Acceptability

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

- Modules B, BH, DA, DB and Global Options (SIP/SOP module) have basic insulation between the mains input and DC outputs. --
- These power supplies have been assessed as a component part of a host equipment. --
- This product range is available as a forced air cooled version (in-built fan) with screw terminal input connections or an IEC 60320 inlet. It is also available as customer air cooled versions (with and without a cover) where the end cap is not fitted and the customer must provide an air flow and measure appropriate temperatures of components within the product. --
- Units utilising 'C' and/or 'CM' output modules have Reinforced insulation between the mains input and DC outputs. The requirements of clauses 17.a and 17.g shall be considered in the end use application. Refer to the Isolation Diagram and associated table for further guidance. --
- Except for permanently installed equipment and IEC60320 dual fused inlet models, the overall equipment in which these products are installed must be fitted with double pole fusing. --
- Insulation between the secondary (PSU output) and earthed chassis is 'functional only' except for units utilising 'CM' output modules only, which have Basic insulation, at the Working Voltage only, provided that no part of the module is fitted in slot location 1 (left hand side looking from module end of PSU). --

- Screw terminals are suitable for factory wiring only. For models with IEC60320 inlet connectors the IEC inlet face of the enclosure has been evaluated as operator accessible . --
- Electrical and fire enclosures are to be provided in the end-use application. --
- If outputs are connected in series and if the total voltage of the outputs connected in series exceeds the 60Vdc SELV limit, then all outputs must be considered non-SELV. --
- This product must be earthed (class I) --
- This equipment has been evaluated for Continuous Power. If intended for use with intermittant power where the average power is higher than the maximum continuous output power evaluated within this report (350W total at input voltages between 90-100Vac, or 664W total at input voltages between 90-100Vac), the Power Input, Normal Temperature and Abnormal Operation tests shall be re-considered. --
- Evaluation for compliance with 6.8.2c) shall be considered in the end use equipment. --
- Electrical and fire enclosures provided as part of end-installations --
- Consideration shall be given to the requirements of clause 57.5 when installed in the end equipment. --