UL TEST REPORT AND PROCEDURE

Standard:	ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10)(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)
Certification Type:	Component Recognition
CCN:	QQHM2, QQHM8 (Power Supplies, Medical and Dental)
Product:	Switch mode power supply
Model:	NV300 and NV-300 Series (See model differences for details of models and nomenclature).
Rating:	100-240Vac nom, 5Arms max, 45-63Hz.
Applicant Name and Address:	TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE DEVON EX34 8ES UNITED KINGDOM

This is to certify that representative samples of the products covered by this Test Report have been investigated in accordance with the above referenced Standards. The products have been found to comply with the requirements covering the category and the products are judged to be eligible for Follow-Up Service under the indicated Test Procedure. The manufacturer is authorized to use the UL Mark on such products which comply with this Test Report and any other applicable requirements of UL LLC ('UL') in accordance with the Follow-Up Service Agreement. Only those products which properly bear the UL Mark are considered as being covered by UL's Follow-Up Service under the indicated Test Procedure.

The applicant is authorized to reproduce the referenced Test Report provided it is reproduced in its entirety.

UL authorizes the applicant to reproduce the latest pages of the referenced Test Report consisting of the first page of the Specific Technical Criteria through to the end of the Conditions of Acceptability.

Any information and documentation involving UL Mark services are provided on behalf of UL LLC (UL) or any authorized licensee of UL.

Prepared by: Ermanno Rebecchi Reviewed by: Dennis Butcher

Supporting Documentation

The following documents located at the beginning of this Procedure supplement the requirements of this Test Report:

A. Authorization - The Authorization page may include additional Factory Identification Code markings.

B. Generic Inspection Instructions -

i. Part AC details important information which may be applicable to products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of this Test Report.

ii. Part AE details any requirements which may be applicable to all products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of each Test Report.

iii. Part AF details the requirements for the UL Certification Mark which is not controlled by the technical standard used to investigate these products. Products are permitted to bear only the Certification Mark(s) corresponding to the countries for which it is certified, as indicated in each Test Report.

Product Description

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

Model Differences

Input Parameters

NOMINAL INPUT VOLTAGE RANGE	100 - 240V AC
INPUT FREQUENCY	45- 63 Hz
MAXIMUM INPUT CURRENT	5A rms
INRUSH CURRENT	<15A AT 25°C

All ratings apply for ambient temperatures up to 50°C. From 50 to 65°C the total output power and the module current ratings are both derated at 2.5% per deg C.

Output Parameters
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 (ATX)	Fixed	1A	12
	N5	13.5 (ATX)	Fixed	1A	13.5

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/12.5A15V/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

- 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) : For building into host equipment
- Mode of operation : Continuous
- Supply connection : For building into host equipment
- Accessories and detachable parts included : None
- Other options include : None
- 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.

Engineering Conditions of Acceptability

For use only in or with complete equipment where the acceptability of the combination is determined by UL LLC. When installed in an end-product, consideration must be given to the following:

- The insulation (separation) for these products is Basic insulation (1MOOP) 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 and CH3
- The following secondary voltages are at non-hazardous energy levels: CH2, 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.

Additional Information

This report has been generated, to provide upgraded standard report, based on the IEC60601-1 2nd edition report E349607-A31 issued by UL International Demko A/S.

Additional Standards

The product fulfills the requirements of: 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)

Markings and instructions	
Clause Title	Marking or Instruction Details
Model	Model number
Company identification	Classified or Recognized company's name, Trade name, Trademark or File
Supply Connection	Voltage range, ac/dc, phases if more than single phase
Alternating current	
Supply Frequency	Rated frequency range in hertz
Power Input	Amps, VA, or Watts
Special Instructions to UL Representative N/A	

Production-Line Testing Requirements

Test Exemptions - The following models are exempt from the indicated test

Model	Grounding Continuity	Dielectric Voltage Withstand	Patient Circuit Dielectric Voltage Withstand
N/A			

Solid-State Component Test Exemptions - The following solid-state components may be disconnected from the remainder of the circuitry during either Dielectric Voltage Withstand Test:

Component
N/A

Sample and Test Specifics for Follow-Up Tests at UL

The following tests shall be conducted in accordance with the Generic Inspection Instructions

Plastic Enclosure or Part	Test	Sample(s)	Test Specifics
N/A			