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Report Reference #

E349607-A6-UL

## UL TEST REPORT AND PROCEDURE

<b>Standard:</b>	UL 60601-1, 1st Edition, 2006-04-26 (Medical Electrical Equipment, Part 1: General Requirements for Safety) CAN/CSA-C22.2 No. 601.1-M90, 2005 (Medical Electrical Equipment - Part 1: General Requirements for Safety)
<b>Certification Type:</b>	Component Recognition
<b>CCN:</b>	QQHM2, QQHM8 (Power Supplies, Medical and Dental)
<b>Product:</b>	Component Power Supply
<b>Model:</b>	NV350, NV-350, NF350 or NV3 Range  (See enclosure 7-01 for details of model configurations)
<b>Rating:</b>	100-240Vac nominal (90-264V max. tolerance), 47-63Hz, 5.5A (See enclosure 7-01 for details of model ratings)
<b>Applicant Name and Address:</b>	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: Wojciech Czerniak (Project Handler) Reviewed by: Dennis Butcher (Reviewer)

#### **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

#### 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.

### Technical Considerations

- 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
- 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**

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:

- 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 intermittent 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.

#### **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.