

**Description****UL TEST REPORT AND PROCEDURE**

<b>Standard:</b>	CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14, AAMI ES60601-1:2005, ES60601-1:2005/AMD1 1:2012 , ES60601-1:2005/AMD2:2021
<b>Certification Type:</b>	Component Recognition
<b>CCN:</b>	QQHM2, QQHM8
<b>Complementary CCNs:</b>	
<b>Product:</b>	Medical Switch Mode Power Supply
<b>Model:</b>	NV350 or NV3 or NV-350, followed by abcde  (may be prefixed by NS - # / or - where # may be up to any four letters and may be followed by - \$; where \$ maybe any number between 000 to 999, indicating non-safety related model differences. Units may be additionally marked with a product code: K3x or Q3x where x may be any number of characters). (Where:- a = Airflow option (which can be S, R, Q, P, V, C, T, U, K or L), b = Input option (which can be S or I), c = Leakage option (which can be S, M, L, R or T) optionally followed by d = Global option (which can be EN#V, EN12V, EN13.5V, IN#V, IN12V, IN13.5V, ES#V, ES12V, ES13.5V, IS#V, IS12V or IS13.5V) # represents the standby output voltage and is in the range 5 to 5.5V. e = modules)  K300yy# (where yy can be 45x, 52x, which x is for revision changes not affecting safety. Where # can be any letter denoting non-safety related changes, e.g. extra labels on the unit and x is for revision changes not affecting safety.)  See report Model Differences for details.
<b>Rating:</b>	100-240Vac nominal (85-264V max. tolerance), 47-63Hz, 5.5A  (See model differences)
<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 as applicable.

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

Prepared by: Maggie Chiu (Project

Reviewed by: Grzegorz Kowalski, Reviewer

Handler)

### 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

The NV350 series are switch mode power supplies for building into 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 a customer air cooled version where the end cap is not fitted and the customer must provide an air flow and measure appropriate temperatures of components within the product.

Refer to the Report Modifications page for any modifications made to this report.

### Model Differences

Unit Configuration Code:

NV350 or NV3 or NV-350 followed by abcde (these models are identical)

(may be prefixed by NS - # / or - where # may be up to any four letters and may be followed by - \$; where \$ maybe any number between 000 to 999, indicating non-safety related model differences)

Unit Configuration Code (Description :) may be prefixed by SP followed by / or – (SP represents a sales code). Units may be additionally marked with a product code: K3x or Q3x where x may be any number of characters).

Where a = S, R, Q, P, V, C, T, U, K or L where:

Option Letter	Airflow Option
S	Forward airflow, standard fan
R	Reverse airflow, standard fan
Q	Forward airflow, quiet fan
P	Reverse airflow, quiet fan
V	Forward airflow, temperature controlled fan
C	Customer air, fan not fitted
T	Forward airflow, top fan
U	Customer air, fan not fitted, cover not fitted
K	Custom fan/chassis assembly
L	Fixed speed fan (see non-standards below)

Where b = S or I where:

Option Letter	Input Option
S	Screw input terminals
I	IEC input

Where c = S, M, L, R, or T, where:

Option Letter	Leakage Option
S	Standard Leakage (Class B Filter)
M	Medium Leakage
L	Low Leakage
R	Reduced Leakage
T	Tiny Leakage

Unit configuration may be given using the above code and/or by the option description. The input terminal type (screw or IEC) may alternatively be determined by examination of the unit.

Optionally followed by d = EN#V, EN12V, EN13.5V, IN#V, IN12V, IN13.5V, ES#V, ES12V, ES13.5V, IS#V, IS12V or IS13.5V. Where:

Description	Option Description
EN#V	AC good, global module good, PSU enable, 5-5.5V, 2A standby output
EN*V	AC good, global module good, PSU enable, 12-13.5V, 1A standby output
IN#V	AC good, global module good, PSU inhibit, 5-5.5V, 2A standby output
IN*V	AC good, global module good, PSU inhibit, 12-13.5V, 1A standby output
ES#V	AC good, PSU enable, 5-5.5V, 2A standby output
ES*V	AC good, PSU enable, 12-13.5V, 1A standby output
IS#V	AC good, PSU inhibit, 5-5.5V, 2A standby output
IS*V	AC good, PSU inhibit, 12-13.5V, 1A standby output

Where: # represents the standby output voltage and is in the range 5 to 5.5V.

Where \* represents the standby output voltage and is in the range of 12-13.5V.

The Global Options Inhibit and Enable functions permit the customer to turn off or on the main PSUs outputs and the fan. The standby supply is for use by the customer and provides an ES1 output that continues to operate when all the main PSUs outputs have been turned off using the Inhibit or Enable functions. All the functions of the Global Option pass through a single 8 way PWB socket and are all rated ES1.

Where e = NV350 or NV3 or NV-350 Modules:

Up to 3 of the following modules types may be fitted:

@B  
or @BH  
or @C  
or @CM

where @ is the output voltage of the module and is within the range given in the single output module table.

or @/#DB (/ can be replaced with a \_)

where @ is the output voltage of channel 1 and # is the output voltage of channel 2 of the module. Voltages are within the range given in the DB module tables.

or @/#DA (/ can be replaced with a \_)

where @ is the output voltage of channel 1 and # is the output voltage of channel 2 of the module. Voltages are within the range given in the DA module tables. Only 1 DA module may be fitted.

or B/S

where B/S indicates that a blanking plate is fitted in place of a module.

The following nomenclature may optionally be used for outputs connected in series:  
(Note that outputs may be connected in series even when this nomenclature is not used)

@BB or @ BHB or @BBH or @BHBH or @CC or @CCM

where @ is the total voltage of any two B, BH, C or CM modules connected in series.

or @/#BDB or @BHDB (/ can be replaced with a \_)

where @ is the total series voltage of any B or BH module and DB module channel 1. # is the output voltage of the DB module channel 2. Voltages for # are within the range given in the DB module tables.

or @HDB

where @ is the total series voltage of any DB module channel 1 and channel 2.

**Note.**

For all outputs connected in series:

Series modules are non-standard units.

Refer to the Instruction Manual for Energy Source Classification of series modules.

Permissible min. value for @ is given by summing the min. voltage ratings of the outputs connected in series.

Permissible max. value for @ is given by summing the max. voltage ratings of the outputs connected in series.

Note: Series connection of one NV350 unit to another NV350 unit is not permitted.

**Custom Models:**

Model: NV350 LSS 24/24DB 15.5/5.5DB (K30045A)

Maximum outputs: 24V, 1A; 24V, 0.7A; 15.5V, 6.4A; 5.5V, 6.4A. (total power 175W max.)

Maximum ambient: 50°C

Orientations: Horizontal with chassis lowest, on either side.

Comments: PSU has fan drive voltage fixed at 5.5V.

Model: NV350 LSS 24/24DB (K30045B)

Maximum outputs: 24V, 7A; 24V, 0.7A. (total power 184.8W max.)

Maximum ambient: 50°C

Orientations: Horizontal with chassis lowest, on either side.

Comments: PSU has fan drive voltage fixed at 5.5V.

Model: NV350 TSS 24B 15BH 5/15DB (K30052X, where X can be any character)

Maximum outputs: 350W max.

Comments: PSU has top fan fitted.

**ELECTRICAL & THERMAL RATINGS:**

**Input Parameters**

Nominal input voltage (V) 100 - 240

Input voltage range (V) 85 - 264

Input frequency range (Hz) 47 - 63

Maximum input current (A) 5.5

Inrush Current (A) <15

For input voltages between 85 and 89.9V the output power is derated to 94% of the values given in the Cooling Options Table.

**Output Modules:**

Module	Output Voltage	Slots	Maximum Average Current According to Slot Position (A)				
			Slot 1	Slot 2	Slot 3	Slot 4	Slot 5



exceeded when remote sense is used.

#### Cooling Options:

Code	Cooling Option	Input Voltage Range (Vac)	Total PSU output power (W)	Max. ambient (°C)
	Derating †			
S, V, T	Forward airflow, standard fan (fixed speed & temp. controlled)	90 - 264 ‡	350 W continuous	65
	(400W peak if 350W average #) 65	2.5% per °C above 50°C		
S, V	Forward airflow, standard fan (fixed speed & temp. controlled)	115 - 264	450 W continuous	65
	(510W peak if 450W average #) 65	2.5% per °C above 50°C		
S, V, T	Forward airflow, standard fan (fixed speed & temp. controlled)	180 - 264	664 W continuous	65
	(740W peak if 600W average #) 65	2.5% per °C above 50°C		
R	Reverse airflow, standard fan	90 - 264 ‡	250 W continuous (no peak rating)	65
	2.5% per °C above 50°C			
Q	Forward airflow, quiet fan	90 - 264 ‡	350 W continuous (no peak rating)	65
	2.5% per °C above 50°C			
T	Top fan for model K30052x only	90 - 264 ‡	350 W continuous (no peak rating)	65
	2.5% per °C above 50°C			
P	Reverse airflow, quiet fan	90 - 264 ‡	250 W continuous (no peak rating)	60
	3.8% per °C above 50°C			
C, U	Customer air, fan not fitted	Refer to Customer Air Cooling section in for details.		

† Both the total output power and the module output currents are derated by the given value.

‡ For input voltages between 85 and 89.9V the output power is derated to 94% of the values given for 90V input.

# The PSU may output the given peak power for up to 10 seconds providing that the average power from the PSU does not exceed the stated value.

Continuous, peak and average power ratings may be linearly interpolated for input voltages between 90 and 180V.

Global Option standby outputs (12-13.5V at 1A or 5-5.5V at 2A) should not be included when calculating total PSU output power, but they are subject to the current deratings for operation above 50°C.

Global Options with output voltages between 5.01 and 5.5V have their max. output current linearly derated from 2A at 50°C ambient to 1.4A at 65°C ambient.

For reverse airflow cooling all B, BH and DB modules are limited to a maximum output power of 150W (total for both channels on dual output modules).

#### Additional Information

The following tests were selected as representative of the test program applicable to model covered by this CBTR:

4.11 POWER INPUT 8.4.3 VOLTAGE OR CHARGE LIMITATION 8.7.4.6 TOUCH LEAKAGE CURRENT  
8.8.3 DIELECTRIC VOLTAGE WITHSTAND 11 TEMPERATURE 13 ABNORMAL OPERATION TESTING  
15.3.2 ENCLOSURE FORCE

These tests have been witnessed for models selected as representative of the standard covered by this report and the applicable test program.

#### Technical Considerations

- The product was investigated to the following additional standards: JIS T 0601-1:2023
- The following additional investigations were conducted: N/A
- 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), Risk management Evaluation
- The following accessories were investigated for use with the product:
- 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 anesthetics mixture with air or oxygen or with nitrous oxide: No  
The product is Recognized only to the following hazards: Fire , Shock  
Product evaluated for an operating temperature of 50°C (full load); 65°C (See enclosure 7-01 for details).

The product was assessed for an operational altitude of 5000m. Multi-layer PWB's accepted under CBTR Ref. No. E349607-A23 dated 2014-07-31 and letter report, Enclosure section.

### 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 2 MOOP between the mains input and DC outputs. The requirements of clause 8.5 shall be considered in the end use application. Refer to the Isolation Diagram and associated table for further guidance.

The component shall be installed in compliance with the enclosure, mounting, marking, spacing, and separation requirements of the end use application.

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 2 MOPP between the mains input and DC outputs. The requirements of clause 8.5 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 and earthed chassis is functional except for units utilising 'CM' output modules only, which additionally have 1 MOPP at a working voltage of 32Vdc. See Table to Insulation Diagram for details.

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.

The equipment shall be properly bonded to protective earth in the end-product application.

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.

The end product should ensure that the requirements related to accompanying documents, clause 7.9, are met.

End product Risk Management Process to include consideration of requirements specific to the Power Supply.

End product Risk Management Process to consider the need for simultaneous fault condition testing.

End product Risk Management Process to consider the need for different orientations of installation during testing.

Components were secured to prevent movement, however end product to determine the acceptability of risk in conjunction to the movement of components as part of the power supply.

End product to determine the acceptability of risk in conjunction to temperature testing without test corner as part of the power supply.

End product to determine the acceptability of risk in conjunction to the selection of components as it pertains to the intended use, essential performance, transport, storage conditions as part of the power supply

Except for permanently installed equipment, the overall equipment in which these products are installed must be fitted with double pole fusing.

The available voltage for the secondary outputs does not exceed 42.4 V peak or 60 V dc, under normal and single fault conditions. However, if outputs are connected in series and the total voltage of the outputs exceeds the 60Vdc SELV limit, then all outputs must be considered non-SELV.

The maximum working voltages measured between Primary to Ground is 343Vrms, 622Vpk and Primary to Secondary is 363Vrms, 650Vpk. Dielectric Voltage Withstand conducted on an end product shall be based on these values.

Inductors and Transformer (TX1) have an Insulation Class F (155).

Considerations to the applied parts requirement, to be conducted as end-product.

Consideration should be given to measuring the temperature on power electronic components and transformer windings when the power supply is installed in the end-use equipment. The end-use product shall ensure that the power supply is used within its ratings.

The output circuits have not been evaluated for direct patient connection (Type B, BF or CF). The input/output connectors are not acceptable for field connections, they are only intended for factory wiring inside the end-use product.

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.

The products were tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.

End product Risk Management Process to consider the acceptability of risk for the following components that were identified as High-Integrity Component: i.e. Fuse (F1).

End product to determine the acceptability of risk in conjunction to insulation to resistance to heat, moisture, and dielectric strength.

End product to determine the acceptability of risk in conjunction to the routing of wires away from moving parts and sharp edges as part of the power supply.

End product to determine the acceptability of risk in conjunction to the Cleaning and Disinfection Methods as part of the power supply.

End product to determine the acceptability of risk in conjunction to the Leakage of Liquids as part of the power supply.

End product to determine the acceptability of risk in conjunction to the Arrangement of Indicators as part of the power supply.

End product to determine the acceptability of risk in conjunction to the results of Mechanical Testing conducted as part of the power supply

The PSU may output the given peak power for up to 10 seconds. When installed in an end product it shall ensure that the average power from the PSU does not exceed the stated value.

Repeat of leakage current testing and consideration of non-frequency weighted leakage test (Clause 8.7.3e) shall be considered in the end product application.

Patient Circuit Dielectric Voltage Withstand production line testing was not conducted. This should be considered as part of the end product evaluation.