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# **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: Switching Power Supply Model: MINT1150VXXYYZWW where V is A (Class I construction) or B (Class II construction), XX represents output voltage which may be any number from 12 to 56, YY represents any number 00 through 99, Z represents A to Z, WW represents additional configurations indicating non-safety related options which may be any number 00 through 99. Input: 100-240Vac, 50-60Hz, 2.0A Rating: Output: With 200 LFM (linear feet per minute) forced air flow: Main Output: 12Vdc/12.5A to 56Vdc/2.68A, Maximum 150W Without forced air flow: Main Output: 12Vdc/8.33A to 56Vdc/1.79A, Maximum 100W\* \*Maximum output power of models MINT1150V12YYZWW is 95W when the input voltage is from 100Vac to 105Vac. SL POWER ELECTRONICS CORP Applicant Name and Address: **BLDG A** 6050 KING DR VENTURA CA 93003 UNITED STATES

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: Karen Shu Reviewed by: Jimmy Deng

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# **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.

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# **Product Description**

The MINT1150VXXYYZWW series, where V is A (Class I construction) or B (Class II construction) are open-frame AC/DC power supplies, designed for building-in to an end-product used in a hospital or related health care facility environment.

The power supplies output can be maximum 150W with 200 LFM (linear feet per minute) forced air flow, or de-rated to maximum of 100W without forced air flow.

## **Model Differences**

The MINT1150AXXYYZWW series is Class I type; MINT1150BXXYYZWW series is Class II type.

Class I construction installs a metal pillar for connecting to protective earth, which Class II construction does not have. Class I construction installs a pair of capacitors (C107, C108) from Mains lines to protective earth, which Class II construction does not have.

All Models are identical in circuit with exception to the Mains Transformer T200 and minor secondary components that allow for different output voltage ratings. There are four types of Mains Transformer T200 in the series of power supply, difference is number of turns on secondary winding. Number of turns and diameter on Primary winding used in model MINT1150V56YYZWW series are different from other models. Refer to Enclosure 4-01 for details.

# **Technical Considerations**

- Classification of installation and use : For built-in
- Device type (component/sub-assembly/ equipment/ system) : Component, Power Supply
- Intended use (Including type of patient, application location): To supply regulated power to end products.
- Mode of operation : Continuous
- Supply connection : Built-in
- Accessories and detachable parts included : None
- Other options include : None
- The product was investigated to the following additional standards:: 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), 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), EN 60601-1: 2006 + CORR: 2010 (Medical electrical equipment Part 1: General requirements for basic safety and essential performance)
- The product was not investigated to the following standards or clauses:: Scope of Power Supply evaluation defers the following clauses to the be determined as part of the end product: Clause 4.2

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(Risk Management), Clause 7.5 (Safety Signs), Clause 7.9 (Accompanying Documents), Clause 9 (ME Hazard), Clause 10 (Radiation), Clause 14 (PEMS), Clause 16 (ME Systems), Clause 17 (Electromagnetic Compatibility).

- 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
- Software is relied upon for meeting safety requirements related to mechanical, fire and shock: No
- The product was submitted and evaluated for use at the maximum ambient temperature (Tma): 50°C.
- The product is Classified only to the following hazards: Casualty, Fire, Shock
- Power Supply was considered Overvoltage Category II.

#### **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 products were tested on a 20A branch circuit, if use on a branch circuit greater than 20A, additional tests may be necessary.
- The component shall be installed in compliance with the Marking (clause 7) and Separation (clause 8) requirements of the end use application.
- 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.
- Transformer T200 provided with a Class B (130°C) insulation system.
- The end product should ensure that the requirements related to accompanying documents, clause 7.9, are met.
- This power supply has been evaluated as continuous operation, ordinary equipment and has not been evaluated for use in the presence of a flammable anaesthetic mixture with air, oxygen, or nitrous oxide. The output circuits have not been evaluated for direct patient connection (Type B, BF or CF).

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- The secondary output circuit of the product is SELV.
- End product Risk Management Process to include consideration of requirements specific to the Power Supply.
- Single fault testing was conducted without dielectric breakdown, however 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.
- Humidity testing was conducted, however the end product Risk Management Process to determine risk acceptability criteria.
- Temperature Test was conducted without Test Corner. End product to determine the acceptability of risk with respect to insulation's resistance to heat, moisture, and dielectric strength per 8.8.4.
- 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.
- Leakage current testing should be considered in the end product application.
- For Class I configuration, Two MOPP is provided between primary and secondary; One MOPP is provided between primary and earth (chassis), operational insulation provided between secondary and earth. For Class II configuration, Two MOPP is provided between primary and secondary.
- The input/output connectors are suitable for factory wiring only and not acceptable for field connections; they are only intended for connection to mating connectors of internal wiring inside the end-use machine.
- Limitation of Voltage/Energy test (8.4.3) was not conducted and should be considered in the end product evaluation.
- The reference voltage for Dielectric Voltage Test in End Product: 472Vpk.

### Additional Information

The schematics for these models are kept in file at the CB Testing Laboratory mentioned in the first page of this test report, and can be provided by the manufacturer upon request by NCB's/CBTL's.

When submitting this Test Report to other Certification Body, the manufacturer is responsible for providing any additional information that the Body may need in order to issue its Mark, including testing for compliance with the applicable collateral standards.

The Electrical and Nameplate Labels are representative of all models in the series.

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The risk management requirements of the standard were not addressed.

### **Additional Standards**

The product fulfills the requirements of: The product fulfills the requirements of: 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); 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); EN 60601-1:2006 + CORR:2010 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

Markings and instructions				
Clause Title	Marking or Instruction Details			
Company identification	Classified or Recognized company's name, Trade name, Trademark or File			
Model	Model number			
Alternating current				
Supply Connection	Voltage range, ac/dc, phases if more than single phase			
Direct current				
Supply Frequency	Rated frequency range in hertz			
Power Input	Amps, VA, or Watts			
Output	Rated output voltage, power, frequency.			
Fuses	Ratings (current and voltage) and type. (located adjacent to fuse OR as a diagram inside enclosure)			
Class II Mark	Only for Class II type models.			
Protective earth ground Mark	Only for Class I type models.			
Special Instructions to UL Representative				
N/A				

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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	
MINT1150VXXYYZWW	Exempt	Exempt	Exempt	
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				