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:	Medical Switching Power Supply, AC-DC Power Supply
Model:	TU425S18EXX, MU425S18EXX (XX=00-99, or blank), MC425D2412EF
Rating:	Input: 100-240V~, 50-60Hz, 4.5A Output: For convection: Main output: 18Vdc/14.67A max Fan output: 12Vdc/0.5A max Standby output: 5Vdc/2.0A max For 200 LFM airflow: Main output: 18Vdc/21.45A max Fan output: 12Vdc/1.0A max Standby output: 5Vdc/2.0A max MC425D2412EF: 400 W max total power with 15 cfm integral fan Main output: 24Vdc/15.7A max Standby output: 5Vdc/2.0A max Main output 2: 12 Vdc/8.0A max Fan output: 12Vdc/1.0A max
Applicant Name and Address:	SL POWER ELECTRONICS CORP 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: Melissa DeGuia Reviewed by: Bernadette Matsuoka

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 TU425S18EXX, MU425S18EXX, and MC425D2412EF are open frame AC/DC power supplies designed for building-in to and end-product used in a hospital or related health care facility environment.

Model Differences

All models are identical to each other except for model designation.

Model MC425D2412EF is similar to TU425S18EXX and MU425S18EXX, except the main output is 24 Vdc. In addition, a buck regulated output PWB (24Vdc to 12Vdc/8.0A) and fan/cover are added.

Technical Considerations

- Classification of installation and use : Building-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 : Building-in, to be determined in end product
- Accessories and detachable parts included : None
- Other options include : None
- The product was investigated to the following additional standards:: EN 60601-1: 2006 + CORR: 2010 + A11 (2011) +A12 (2014) (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 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
- Manufacturer’s Recommended Ambient: 50°C
- The product is Classified only to the following hazards: Casualty, Fire, Shock
- Power Supply was considered Overvoltage Category II (OVCII)

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 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.
- Transformers are provided with a Class F (155º) insulation system: T300 and T201. ,
- 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).
- The available voltage for the secondary outputs does not exceed 25 Vac or 60 Vdc, under normal and single fault conditions.
- 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.
- 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.
- Power supply main output of 18Vdc and 24Vdc exceeds the energy limit (240 VA) per 8.4.2.c and considered Hazardous Energy. Accessibility and compliance to be determined in the end-product evaluation.
- The expected service life of this product is 5 years.
- Two MOPP is provided between primary and secondary; One MOPP is provided between primary and earth (chassis), operational insulation provided between secondary and earth.
- The input/output connectors are not acceptable for field connections; they are only intended for connection to mating connectors of internal wiring inside the end-use machine.
- End product Dielectric Voltage Withstand Test shall be based on the following working voltages of the power supply: 1 MOPP = 592Vpk, 361Vrms and 2 MOPP = 576Vpk, 362Vrms.
- The products were tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.
- Units were tested with 200LFM forced air fan. Additional considerations shall be taken into consideration when installed in an end product with different airflow conditions.
- End product Risk Management Process to consider the need for different orientations of installation during testing.
- Power Supply tested in a max. ambient of 50°C. End product Risk Management Process to determine risk acceptability criteria.
- 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 movement of components as

part of the power supply.

- End product to determine the acceptability of risk in conjunction to the movement of conductors as part of the power supply.
- 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.
- Proper bonding to the end-product main protective earthing termination is required.

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. See Photograph ID 3-01 for company logo.

The risk management requirements of the standard were not addressed.

Additional consideration was taken to review the products covered under this Report to EN 60601-1::2006/A11 (2011)+A12(2014). Based upon review of the Amendment, it was deemed not applicable for the models covered under this Report.

We recognize that the TRF used in this file may not be the latest version. However we have reviewed the newest TRF and there are no technical changes from the one that was used for this report. All changes are administrative only.

Amendment No. 1 for Project 4786504011
1. Add alternate fuse with 250V, 8.0A.
2. Add “Optional” to L103
3. Minor updates on components

This report is a reissue and upgrade of CBTR Ref. No.: E116994-A103-CB-1, Issued 2014-04-20, CB Test Certificate Ref. No. US-23226-UL and amended on 2014-09-19, 2014-10-09, and 2015-02-05. Based on the limited testing conducted to add Model MC425D2412EF and the review of product technical documentation including photos, schematics, wiring diagrams and similar, has been determined that the product continues to comply with the standard.

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 + A11: 2011 + A12: 2014 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 Frequency	Rated frequency range in hertz
Power Input	Amps, VA, or Watts
Output	Rated output voltage, power, frequency.

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
All models	Not exempt	Not 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			