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:	Other
Model:	MDS-150CAB20 A MDS-150CAB19 A
Rating:	INPUT: 100-240Vac, 2.5-1A, 50-60Hz OUTPUT: 20Vdc/7.5A (for MDS-150CAB20 A) 19Vdc/7.9A (for MDS-150CAB19 A)
Applicant Name and Address:	DELTA ELECTRONICS INC 3 TUNGYUAN RD CHUNGLI INDUSTRIAL ZONE TAOYUAN COUNTY 32063 TAIWAN

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: Zang Lee Reviewed by: Conga Chen

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 equipment is a Class I Switching Power Adapter which electronic components mounted on PWB and housed in plastic enclosure. This unit is intended for general use as a component of medical electrical equipment and systems.

The adaptor has one insulation transformer (T1) and the insulation system of the equipment was evaluated for compliance with the means of patient protection (MOPP) per applicant's request.

The output cord is non-detachable and located at the opposite side of the inlet. The top and bottom plastic enclosures are fixed with ultrasonic welding.

The maximum operation ambient temperature and altitude specified by the manufacturer are +40 °C and 5000m.

Model Differences

Models MDS-150CAB20 A and MDS-150CAB19 A are identical with each other excepted for output rating, model designation and component ratings of R134 and R135 located on the secondary side.

For Model MDS-150CAB20 A:
R134, 15.8 Kohm
R135, 15 Kohm

For Model MDS-150CAB19 A:
R134, 16.2 Kohm
R135, 16 Kohm

Technical Considerations

- Classification of installation and use : Portable
- Device type (component/sub-assembly/ equipment/ system) : Component
- Intended use (Including type of patient, application location) : N/A - Recognized component
- Mode of operation : Continuous
- Supply connection : Appliance coupler

- 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), CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance), IEC 60601-1 3RD ED. MEDICAL ELECTRICAL EQUIPMENT PART 1: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - Edition 3 - Revision Date 2013/05/01, EN 60601□1:2006/ A11:2011
- The product was not investigated to the following standards or clauses:: Electromagnetic Compatibility (IEC 60601-1-2), Biocompatibility (ISO 10993-1)
- The degree of protection against harmful ingress of water is:: IP22
- 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

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:

- This power supply has been judged on the basis of the required Creepage and Clearances according to Clause 8.9 in the ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10), CAN/CSA-C22.2 No. 60601-1 (2008), IEC 60601-1 3RD ED. and EN 60601□1:2006/A11:2011 that cover the end-use application for which the component was designed.
- This power supply has been evaluated as a Class I, continuous operation, ordinary Equipment and has not been evaluated for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. An additional evaluation shall be made if the power supply is intended for use in other than Class I equipment.
- Considerations to the applied part requirements should be evaluated in the end application.
- The output circuits have not been evaluated for direct patient connection (Type B, BF or CF). For end application intend to connect the output circuit to Applied Parts, suitable evaluation of the separation, leakage current, dielectric voltage withstand, and related requirements should be conducted.
- This power supply was tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.
- Consideration should be given to measuring the temperatures on power electronic components and transformer windings when the power supply is installed in the end application. The end application shall ensure that the power supply is used within its ratings. Transformer T1 is rated Class B (130 °C).
- This power supply provides the following MOPP (means of patient protection): 2 MOPP based upon a working voltage 250 Vrms, 470 Vpk between Primary to Secondary (Core is considered as primary side), 2 MOPP based upon a working voltage 250 Vrms, 354 Vpk between Primary to Enclosure, and 1 MOPP based upon a working voltage 250 Vrms, 354 Vpk between Primary to Earth. See insulation diagram for details.
- Temperature, Leakage Current, Protective Earthing, Dielectric Voltage Withstand, and Interruption of the Power Supply tests should be considered as part of the end application evaluation.
- Test corner should be evaluated in end application.

- The component should be properly bonded to ground in the end application.
- The end-product evaluation shall ensure that the requirements related to Accompanying Documents, Clause 7.9 are met.
- The Legibility of Markings test for Label should be considered in the end application
- The degree of protection against harmful ingress of water is IP22. This was not evaluated by UL, See enclosure ID 7-01 for testing report made by Electronics Testing Center, Taiwan (ETC).

Additional Information

The degree of protection against harmful ingress of water is IP22. This was not evaluated by UL, See enclosure ID 7-01 for testing report made by Electronics Testing Center, Taiwan (ETC).

Additional Standards

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) CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) IEC 60601-1 3RD ED. MEDICAL ELECTRICAL EQUIPMENT PART 1: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - Edition 3 - Revision Date 2013/05/01 EN 60601-1:2006/ A11:2011

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
Supply Connection	Voltage range, ac/dc, phases if more than single phase
Alternating current	
Supply Frequency	Rated frequency range in hertz
Direct current	
Power Input	Amps, VA, or Watts
Output	Rated output voltage, power, frequency.
IP Rating	IP22
Operating Instructions	

Special Instructions to UL Representative

Operating Instructions will be provided in end application.

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
–	--	--	--