UL TEST REPORT AND PROCEDURE

Standard:	ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10 + A1:12)(Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) CAN/CSA-C22.2 No. 60601-1 (2014) (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:	LPT62-M, LPT63-M, LPS63-M, LPS64-M and LPS65-M
Rating:	Input: 100-250 Vac, 50/60 Hz, 2.3 A, or 140-300 Vdc, 1.5 A Output: For Model LPT62-M: +5Vdc, 8.0 A; +12Vdc, 3.5 A; -12Vdc, 1.0 A For Model LPT63-M: +5Vdc, 8.0 A; +15Vdc, 3.3 A; -15Vdc, 1.0 A For Model LPS63-M: +12Vdc, 6.7 A For Model LPS64-M: +15Vdc, 5.34 A For Model LPS65-M: +24Vdc, 3.33 A Maximum continuous output power is 60W with convection cooling, and 80W with 30CFM forced-air cooling at 50°C ambient temperature.
Applicant Name and Address:	Astec International Ltd - Philippine Branch 16th Floor Lu Plaza, 2 Wing Yip Street, Kwun Tong, Kowloon, Hong Kong

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.

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

Prepared by: Clare He Reviewed by: Calvin Tang

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

This unit is a medical switching mode power supply for building-in which has been evaluated for use in Class I medical application. Unit provided with an insulation transformer and all components are mounted on UL94 V-0 PWB.

Model Differences

Models LPT63-M, LPS63-M, LPS64-M and LPS65-M are identical to Model LPT62-M except output rating, number of turns of Transformer T1, and some secondary components.

Technical Considerations

- Classification of installation and use : For built-in
- Device type (component/sub-assembly/ equipment/ system) : Component
- Intended use (Including type of patient, application location) : Recognized power supply for medical equipment usage
- The degree of protection against harmful ingress of water is: IPX0
- Mode of operation : Continuous
- Supply Connection: To be evaluated in end product.
- Accessories and detachable parts included : None
- The product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide: None
- Other options include : None
- The product was investigated to the following additional standards:: ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10 + A1:12) (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 (2014) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes National Differences for Canada).
- The product was not investigated to the following standards or clauses:: Electromagnetic Compatibility (IEC 60601-1-2), Biocompatibility (ISO 10993-1)

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 in the First Edition of the Standard for Medical Electrical Equipment, ANSI/AAMI ES 60601-1 AMD1 Sub clause 8.9.

- 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.

- This power supply was tested on a 20A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.

- The power supply was evaluated as 2 MOPP between Primary to Secondary and 1 MOPP from Primary to Earth see insulation diagram for details.

- Consideration should be given to measuring the temperatures on power electronic components and transformer windings when the power supply is installed in the end use equipment. The transformer (T1) incorporates a Class 155 (F) insulation system.

- The secondary circuit of this power supply has not been evaluated for patient connected applications.

- The following tests shall be performed in the end-product evaluation: Earthing and Potential Equalization Test, Temperature Test, Dielectric Voltage Withstand Tests, Leakage Current Test with Normal MD, Non-frenquency MD and Fuse Short Circuit Test.

- The maximum working voltage for T1 is 250 Vrms, 504 Vpk. The electric strength tests in the end-product shall be based on this value.

- This power supply shall be installed in compliance with the enclosure, mounting, spacing, casualty, markings and segregation requirements of the end use application.

- A suitable Mechanical, Electrical and Fire enclosure shall be provided in the end-use product.

- This power supply is operated up to 3000m above sea level as declared by manufacturer.

- Separation from secondary to earth need to evaluated in end product.

- End product Risk Management Process to include consideration of requirements specific to the Power Supply and the suitability of Fuse.

- The input and output connectors are not suitable for field connection.

- 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.

- 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 and 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.

- Temperature Test was conducted without Test Corner. 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 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.
- 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.
- The end-product evaluation shall ensure that the requirements related to Accompanying Documents, Clause 7.9 are met.
- This power supply has one fuse (F1) rated 3.15A, 250V connected in Live.
- The power supply shall be properly bonded to the main earthing termination in end-use.
- During the evaluation, an external forced air-cooling from input terminal to output terminal with air flow 30CFM is required when installing into the end system.
- Maximum continuous output power is 60W with convection cooling, and 80W with 30CFM forced-air cooling at 50°C ambient temperature.
- Overcurrent releases of adequate breaking capacity must be employed in the end product.