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:	NPS22-M, NPS23-M, NPS24-M, NPS25-M, NPS28-M
Rating:	Input: 100-250V, 1.5A, 50/60Hz or 140Vdc(min.) -300Vdc(max.), 1.0 A. Input power must be less than 49 Watts for models NPS23-M, NPS24-M, NPS25-M, NPS28-M. Input power must be less than 51Watts for model NPS22-M. Model NPS22-M: Output: +5Vdc, 8A max. Model NPS23-M: Output: +12Vdc, 3.3A max. Model NPS24-M: Output: +15Vdc, 2.67A max. Model NPS25-M: Output: +24Vdc, 1.67A max. Model NPS28-M: Output: +48Vdc, 0.834A max. Maximum Output Power: 25VA for Convection Cooling 40VA for Forced Air Cooling
Applicant Name and Address:	ASTEC INTERNATIONAL LTD - PHILIPPINE BRANCH 16TH FL LU PLAZA 2 WING YIP ST 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.

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: Sammi Liang 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 and Class II medical application. Unit provided with an insulation transformer and all components are mounted on 94V-0 PWB.

Model Differences

Model NPS24-M is identical to Model NPS23-M except Output rating and number of turns of Transformer T1.

Models NPS25-M and NPS28-M are similar to Model NPS23-M except output rating and construction of Transformer T1.

Models NPS22-M is similar to Model NPS23-M except output rating, construction of Transformer T1 and minor difference in PWB Layout.

Technical Considerations

- Classification of installation and use : Open frame Component - to be evaluated in end product
- Device type (component/sub-assembly/ equipment/ system) : Component
- Intended use (Including type of patient, application location) : Component - to be evaluated in end product
- Mode of operation : Continuous
- Supply connection : Primary connector - to be evaluated in end product
- 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) - Edition 1 - Revision Date 2012/01/01;, CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) Edition 2 - Revision Date 2011/06/01;, IEC 60601-1: 2005 + CORR.1 (2006) + CORR.2 (2007) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) - Edition 3;
- 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
- The product is Recognized only to the following hazards: Fire, Shock.

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 power supplies have been judged on the basis of the required creepage and clearances in the Standard for Medical Electrical Equipment, ANSI/AAMI ES 60601-1, Sub clause 8.9.
- This power supply has been evaluated for use in Class I or Class II, continuous operation equipment, 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. When the power supply is used as Class II equipment, all PE traces and components connected to PE on the primary side will be treated as primary part for spacing and insulation considerations. If the power supply is intended for use as Class I, the connector (CN1) should be connected and investigate in end system. The earthing and potential equalization test IEC 60601-1, Sub-Clause 18f) should be considered in end system.

- The power supplies were tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.
- The power supplies were evaluated as 2 MOPP provided between Primary and Secondary, and 1 MOPP provided between Primary and 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 primary transformer (T1) incorporates a Class 155 (F) insulation system.
- Total continuous output power shall not exceed 25W with convection cooling and shall not exceed 40W with forced air cooling. Output derates 2.5% per degree from 50degC to 80degC ambient temp.
- The output connectors are not acceptable for field connection and are only intended for connections to mating connectors of internal wiring inside the end use product. The acceptability of these and the mating connectors relative to secureness, insulating materials, and temperatures shall be considered in the end use product.
- A suitable Electrical, Mechanical and Fire enclosure shall be provided in the end use product.
- The end-product Electric Strength Test is to be based upon a maximum working voltage of T1: 320.4 Vrms, 789 Vpk.
- Instructions and equipment marking shall be provided in a language, which is acceptable in the country in which the equipment is to be installed.
- The end product should ensure that the requirements related to accompanying documents, clause 7.9, are met.
- The component shall be installed in compliance with the enclosure, mounting, marking, spacing, and separation requirements of the end use application.
- Input terminal/connector shall be connected to the supply leads in the end use for simultaneous disconnection of all supply poles.
- This secondary circuit of this power supply has not been evaluated for patient connected applications.
- Additional UL Recognized DC Fuse must be provided in end-system for DC input.
- The following tests shall be performed/further considered in the end-product evaluation: Impedance and Current Carrying Capability, Temperature Test, Dielectric Voltage Withstand Tests, Leakage Test and Interruption of Power Supply Test.
- 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.
- 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 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 selection of components as it pertains to the intended use, essential performance, transport, storage conditions as part of the power supply.
- The secondary output circuits of Transformer (T1) are SELV and are not at hazardous energy levels.
- The power supply shall be properly bonded to the main protective earthing termination in the End Product.
- Earthing terminal at input connector is not considered as protective earthing terminal, but is considered as bonding terminal. It should be connected complying with "FILO" and investigated in end use again.
- Ventilation fan should be provided in the end system according to the loading setup direction. Fan stalled consideration should be investigate in the end system.