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:	AC/DC Power Adaptor
Model:	DP4009N2M, DP4012N2M, DP4015N2M, DP4018N2M, DP4024N2M, DP4048N2M
Rating:	Input:100-240Vac, 50/60Hz, 1.0A, 49W Max. Output for Model DP4009N2M: +9 Vdc, 4.44 A Max. Output for Model DP4012N2M: +12 Vdc, 3.33 A Max. Output for Model DP4015N2M: +15 Vdc, 2.67 A Max. Output for Model DP4018N2M: +18 Vdc, 2.22 A Max. Output for Model DP4024N2M: +24 Vdc, 1.67 A Max. Output for Model DP4048N2M: +48 Vdc, 0.84 A Max.
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

These units are switching mode power supply, employs an appliance inlet for plugging in power supply cord (Not provided). A step down isolation transformer is used and all electronic components are mounted on PWB that rated V-0 and housed in plastic enclosure that rated V-0. Output cord is provided and the output plug is polarized and not standardized.

Model Differences

Model DP4012N3M (See Report E182560-A113) is treated as basic model for testing.

Model DP4012N2M is identical to DP4012N3M, except for DP4012N2M is configured as Class II and DP4012N3M is configured as Class I.
Model DP4009N2M is identical to DP4009N3M, except for DP4009N2M is configured as Class II and DP4009N3M is configured as Class I.
Model DP4015N2M is identical to DP4015N3M, except for DP4015N2M is configured as Class II and DP4015N3M is configured as Class I.
Model DP4018N2M is identical to DP4018N3M, except for DP4018N2M is configured as Class II and DP4018N3M is configured as Class I.
Model DP4024N2M is identical to DP4024N3M, except for DP4024N2M is configured as Class II and DP4024N3M is configured as Class I.
Model DP4048N2M is identical to DP4048N3M, except for DP4048N2M is configured as Class II and DP4048N3M is configured as Class I.

Model DP4009N2M is identical to Model DP4012N2M except for alternate output rating, transformer, trimming components and PWB layout.
Model DP4015N2M is identical to Model DP4012N2M except for alternate output rating and transformer.
Model DP4018N2M is identical to Model DP4012N2M except for alternate output rating, transformer and trimming components.
Model DP4024N2M is identical to Model DP4012N2M except for alternate output rating and transformer.
Model DP4048N2M is identical to Model DP4012N2M except for alternate output rating and transformer.

Technical Considerations

- Classification of installation and use : (Hand-held) 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 : 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) - 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;
- 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: Casualty, 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 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 II equipment.
- 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; 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 130 (B) insulation system.
- No power supply cord is provided for this power supply, this item must be considered in the end product usage.
- The suitability of the appliance inlet used shall be determined in end product application for the requirement of CAN/ CSA polarized type plug.
- The end-product Electric Strength Test is to be based upon a maximum working voltage of T1: 273.4 Vrms, 583 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.
- The secondary output circuit is SELV.
- The equipment has not been evaluated for use in or likely to be used in the patient vicinity.
- Additional marking shall be provided per the end product application.
- The following tests shall be performed/further considered in the end-product evaluation: Cleaning, sterilization or disinfection, Temperature Test, Dielectric Voltage Withstand Tests, and Leakage 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 end use application shall insure that the, power supply is used within its ratings.
- The reliability of the Silkscreen printing should be evaluated at end System.
- Maximum Operating Temperature Tma (°C) is 40degC for full load and 60degC for half of the full load.