UL TEST REPORT AND PROCEDURE

Standard:	ANSI/AAMI ES60601-1 (2005/(R) 2012 +A1:2012, C1: 2009/(R) 2012 + A2:2010/(R) 2012) Amendment 1 – Revision Date 2012/08/21.CAN/CSA – C22.2 No. 60601-1:14 – Edition 3 – Revision Date 2014/03.
Certification Type:	Component Recognition
CCN:	QQHM2, QQHM8 (Power Supplies, Medical and Dental)
Product:	Switching Power Supply
Model:	iVS8-ABBC-ABBC-ABBC-ABBC-ABBC-ABBC-ABBC-ABBC-ABBC-ABBC-ABBC-ABBC- ABBC-ABBC-XX (See test report for details of the model description)
Rating:	AC Input Ratings: 200-240Vac, 50/60Hz, 16A, 3W+PE DC Output Ratings: Maximum output power: 4920W See test report for details
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: Cary Hu Reviewed by: Sammi Liang

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 switching mode power supply, employs an appliance inlet for plugging in power supply cord (Not provided). All isolation transformers and all electronic components are mounted on PWB which rated V-0, and covered in PE enclosure. And this power supply is a combination big power module made of several UL 60601-1 evaluated small unit power modules.

Model Differences

N/A

Technical Considerations

- Classification of installation and use : Partially built in - 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: N/A
- 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.
- The risk management requirements of the standard were not addressed.

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, Sub clause 8.9.
- This power supply has been evaluated as a Class I, continuous operation and has not been evaluated for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. 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 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.
- This power supply is a combination big power module made of several UL 60601-1 evaluated small unit power modules. There is no insulation requirement for it.
- Consideration shall be given to measuring the temperatures on power electronic components and transformer windings when the power supply is installed in/with the end-use equipment.
- Maximum recommended ambient (Tma) is 50℃ and 70℃ at derated power. Output Power Rating

(excluding +5VSB): , – Maximum 4920W at up to 50℃ normal airflow and same full-power at up to 40℃ reverse airflow condition. , – Output ratings derate 2.5% per ℃ from 50℃ to 70℃ for normal airflow. ,

- This power supply has not been evaluated for patient connected applications.
- 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 end-use product shall ensure that the power supply is used within its ratings.
- The marking legibility test of the silkscreen printing and labeling should be evaluated in end system.
- The following tests shall be performed in the end-product evaluation: Temperature Test, Dielectric Voltage Withstand Tests, Leakage Test, Interruption of Power Supply and Protective Grounding Test.
- End product Risk Management Process to include consideration of requirements specific to the Power Supply.
- End product Risk Management Process to consider the acceptability of risk for the following components that were identified as High-Integrity Component.
- 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.
- 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 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.
- This unit is intended to be used at 3048m high altitude.
- Clearance distance was evaluated for operating altitude up to 10,000 feet (3048 meters) above sea level. , Clearance / creepage distance and electronic strength were evaluated and fulfilled the requirements for 2MOPP between Primary to Secondary. 1MOPP between Primary to PE, This product have been provided 1MOOP insulation between the polarity of mains parts

- Overcurrent releases of adequate breaking capacity must be employed in the end product.