# UL TEST REPORT AND PROCEDURE

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| **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<br>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:** | 73-959-0001, **73-958-0001** |
| **Rating:** | AC Input:<br>**For model 73-959-0001**<br>3P (3W+PE) AC 380 - 480V, 41A max or<br>208 - 240V, 75A max, 50/60Hz<br><br>**For model 73-958-0001**<br>**380-480V, 21A, 3~, 3W+PE, 50/60Hz or**<br>**200-240V, 40A, 3~, 3W+PE, 50/60Hz or**<br>**200-240V, 68A, 1~, 2W+PE, 50/60Hz**<br><br>Output:<br><br>**For model 73-959-0001**<br><br>DC 5Vsb, 1.0A<br><br>(Section A: 12840 output power)<br>PFC1 Vbus: DC 400V, 5.35A max;<br>PFC2 Vbus: DC 400V, 5.35A max;<br>PFC3 Vbus: DC 400V, 5.35A max;<br>PFC4 Vbus: DC 400V, 5.35A max;<br>PFC5 Vbus: DC 400V, 5.35A max;<br>PFC6 Vbus: DC 400V, 5.35A max<br><br>(Section B: 12840 output power)<br>PFC1 Vbus: DC 400V, 5.35A max;<br>PFC2 Vbus: DC 400V, 5.35A max;<br>PFC3 Vbus: DC 400V, 5.35A max;<br>PFC4 Vbus: DC 400V, 5.35A max;<br>PFC5 Vbus: DC 400V, 5.35A max;<br>PFC6 Vbus: DC 400V, 5.35A max<br><br>Maximum output power is 25685W.<br><br>**For model 73-958-0001**<br><br>**DC 5Vsb, 1.0A**<br><br>**PFC1 Vbus: DC 400V, 5.35A max;**<br>**PFC2 Vbus: DC 400V, 5.35A max;**<br>**PFC3 Vbus: DC 400V, 5.35A max;** |

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| | **PFC4 Vbus: DC 400V, 5.35A max;**<br>**PFC5 Vbus: DC 400V, 5.35A max;**<br>**PFC6 Vbus: DC 400V, 5.35A max**<br><br>**Maximum output power is 12845W.** |
| **Applicant Name and Address:** | ASTEC INTERNATIONAL LTD<br>16TH FL<br>LU PLAZA<br>2 WING YIP ST<br>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: **Skye Mo / Clare He** 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 (permanently installed ME equipment), which employs an input block terminal for connecting the power supply cord (Not provided) or input cable (Not Provided). Isolation transformers are used and all electronic components are mounted on PWB that rated V-0 and housed in a metal enclosure.

**Model Differences**

**Model 73-959-0001 is the same as 73-958-0001 except for derated input current and output power, reduced number of DC-DC slots and reduced overall sized of power supply enclosure.**
**For model 73-959-0001:**

- **Maximum continuous power: 24000W;**
- **With 8 slots of iHP DC-DC modeules;**
- **The back plane is for 8 modules;**
- **The cage is 8 slots;**
- **2 pfc assembly;**
- **The comms assembled vertically;**
- **Two PCB Bulk Aux board;**
- **AC interconnect board with fuse**

**For model 73-958-0001:**

- **Maximum continuous power: 12845W;**
- **The back plane is for 4 modules;**
- **The cage is 4 slots;**
- **1 pfc assembly;**
- **The comms assembled vertically;**
- **One PCB Bulk Aux board;**
- **AC interconnect board without fuse;**
- **Aux fuse board**

**Please refer to Attachment- Miscellaneous for model differences between the two models for details.**

**Technical Considerations**

- Classification of installation and use : Permanently installed
- Device type (component/sub-assembly/ equipment/ system) : Component
- Intended use (Including type of patient, application location) : Recognized power supply for medical equipment usage
- Mode of operation : Continuous
- Supply connection : Permanently installed
- 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:: Biocompatibility (ISO 10993-1), Clause 14, Programmable Electronic Systems, Electromagnetic Compatibility (IEC 60601-1-2)
- The degree of protection against harmful ingress of water is:: Ordinary
- 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 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, 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 100A 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 (ISOCOM user accessible) and 1 MOPP from Primary to Earth, Primary to Mid section and Mid section to Secondary circuits. 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 transformers (T500 & T501) incorporate 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 and Leakage Current Tests.
- The maximum working voltage is 347.1 Vrms, 767 Vpk for Primary - Secondary and 317.4 Vrms, 815 Vpk for Primary - Earth Dead Metal for model 73-959-0001. The electric strength tests in the end-product shall be based on these values or by Client’s request whichever is higher.
- 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 3048m 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.
- The power supply shall be properly bonded to the main earthing termination in end-use and shall be connected permanently.
- Maximum ambient temperature around the power supply must not exceed 50 deg C .
- Overcurrent releases of adequate breaking capacity must be employed in the end product.
- Built-in switching power supply. Applicability of the following is to be determined in End Product Evaluation: 8.4.2 - Limitation of voltage, Current or power.
- The end-product evaluation shall assessment that the requirements of mains terminal device for permanently installed ME equipment Clause 8.11.4.1 are met.
- The power supply is a built-in device as parts of medical equipment. The date of manufacture needs to be evaluated in the end-product.Leakage current test, Temperature test, earth impedance test, legibility test, humidity and dielectric test need to be repeated / considered in end-product investigation.