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:	LPS54-M
Rating:	Rated Input: 100-240 V, 50/60 Hz, 2 A; Rated Output: 15 Vdc, 4 A
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 is a switching mode power supply, open frame type, all electronic components are mounted on V-0 PWB, classified as Class I power supply..

Model Differences

N/A

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) : Switching type power supply for general use with medical electrical equipment.
- Mode of operation : Continuous
- Supply connection : 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: 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 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:

- The power supply is a built-in device as parts of medical equipment. The date of manufacture & S/N marked needs to be evaluated in the end-product.
- 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 20A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.
- The power supply was evaluated as 2 MOOP between Primary to Secondary, 1 MOOP provided between the polarity of mains parts and 1 MOOP from Primary to Earth see insulation diagram for details.
- 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. All transformers employ a Class F (155°C) insulation system.
- The secondary output circuit of the product is SELV.

- 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 Test
- The reference voltage for Dielectric Voltage Test in End Product: 310.7 Vrms, 514 Vpk for T1
- This power supply shall be installed in compliance with the enclosure, mounting, spacing, casualty, markings and segregation requirements of the end use application.
- "Voltage or charge limitation" may need to reconsider if additional EMC filter is provided between appliance inlet/ power cord to the product.
- A suitable Mechanical, Electrical and Fire enclosure shall be provided in the end-use product.
- This power supply is operated up to 3050m 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
- The input and output connectors are not suitable for field connection
- Proper bonding to the end-product main protective earthing termination is required
- 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
- Fuse of Littelfuse, Type 392 does not have adequate breaking capacity 100A; Overcurrent releases of adequate breaking capacity must be employed in the end product.

Additional Information

Original 4787022260: upgrade standard to ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10 + A1:12) and CAN/CSA-C22.2 No. 60601-1 (2014).
The product is certified previously by ANSI/AAMI ES60601-1: 2005 and CAN/CSA-C22.2 No.60601-1:08, 2nd Edition, Refer to E182560-A101 for details.
The risk management requirements of the standard were not addressed.

Comparison previous report, Just modification to some minor information below :

a. Changed all “various” to “interchangeable” in CCL.
b. Changed all “Astec or Artesyn or Emerson” to “Astec or Artesyn” in CCL.

Additional Standards

The product fulfills the requirements of: N/A

Clause Title	Marking or Instruction Details
Company identification	Classified or Recognized company's name, Trade name, Trademark or File
Model	Model number
Supply Connection	Voltage range, ac/dc, phases if more than single phase
Alternating current	
Supply Frequency	Rated frequency range in hertz
Power Input	Amps, VA, or Watts
Output	Rated output voltage, power, frequency.
Fuses	Ratings (current and voltage) and type. (located adjacent to fuse OR as a diagram inside enclosure)
Protective earth ground	

Special Instructions to UL Representative

N/A

Production-Line Testing Requirements

Test Exemptions - The following models are exempt from the indicated test

Model	Grounding Continuity	Dielectric Voltage Withstand	Patient Circuit Dielectric Voltage Withstand
LPS54-M	N/A	No exemption (refer to E182560-A101 for test voltage)	N/A

Solid-State Component Test Exemptions - The following solid-state components may be disconnected from the remainder of the circuitry during either Dielectric Voltage Withstand Test:

Component
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Sample and Test Specifics for Follow-Up Tests at UL

The following tests shall be conducted in accordance with the Generic Inspection Instructions

Plastic Enclosure or Part	Test	Sample(s)	Test Specifics
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TABLE: List of Critical Components

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN /Standard	Marks of Conformity
Marking plate	3M (MH16411)	7815	100 °C, for application to Polycarbonate.	PGJI2/8 UL969	UL/cUL
Label Supplier	Interchangeable	Interchangeable	Various	PGAA	UL
PWB	Interchangeable	Interchangeable	V-0 or Better, 130°C	ZPMV2 / UL 796, UL94	UL
Connector (SK1)	MOLEX	5414 (Marked 41791)	7A, 250V	ECBT2 UL1977	UL
Alternate - Connector (SK1)	WECO	A396-T-DS	10A, 300V	ECBT2 UL1977	UL
Connector (SK2)	Interchangeable	Interchangeable	6 pins provided. Plastic minimum V-1 or better.	QMFZ2 UL746C, UL94	UL
Fuse (F1, F2)	LITTELFUSE WICKMANN WERKE (E67006)	392	T3.15 AL, 250 V. Marked "F1 T3.15AL 250V" and "F2 T3.15AL 250V" on PWB respectively.50A breaking capacity	JDYX2/8 UL248-14	UL/cUL
Fuse (F1, F2)-Alternate	Interchangeable	Interchangeable	Listed, T3.15 AL, 250 V ac. Marked "F1 T3.15AL 250V" and "F2 T3.15AL 250V" on PWB. Min. 100A breaking capacity.	JDYX/7 UL248-14	UL/cUL
X-Cap. (C1) (optional)	Interchangeable	Interchangeable	Min. 250 V, Max. 0.33 µF, Class X1 or Class X2, provided with VDE or SEV marking.	FOKY2/8, FOWX2/8 UL60384-14, IEC60384-14	UL/cUL
Y-Cap (C2, C3)	Interchangeable	Interchangeable	Max. 220 pF, Min. 250 V, Class Y1, provided with VDE or SEV marking.	FOKY2/8, FOWX2/8 UL60384-14, IEC60384-14	UL/cUL
Electrolytic Capacitor (C5, C32)	Interchangeable	Interchangeable	68 µF, minimum 400 V, minimum 105 °C, provided with pressure relief.	-	-
Bridge capacitor (C17) (Optional)	Interchangeable	Interchangeable	Max. 1000 pF, Min. 250 V, Class Y1, provided with VDE or SEV marking.	FOKY2/8, FOWX2/8 UL60384-14, IEC60384-14	UL/cUL
Bridge Diode (DB1)	Interchangeable	Interchangeable	Min 600 V, 4 A.	-	-

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN /Standard	Marks of Conformity
Transistor (Q5)	Interchangeable	Interchangeable	Rated 500 V, 9 A.	-	-
Discharging resistor (R4, R5)	Interchangeable	Interchangeable	Max 470 kohm, Min 1/4 W respectively.	-	-
Opto-coupler (IC2, IC3)	Lite-On Technology Corp.(E113898)	LTV-817	Double Protection, Viso; 5300 V ac.	FPQU2, FPQU8 UL1577	UL/cUL
Opto-coupler (IC2, IC3) - Alternate	Vishay Infrared Components	System code H or J	Double Protection, Viso; 4420 Vac.	FPQU2, FPQU8 UL1577	UL/cUL
Transformer (T1)	Astec or Artesyn	Part No. 8527200060 or 801-004176-XXXX	Class F(OBJY2), Astec, type 155-10C (E94225). See enclosure attachment for T1 spec.	XORU3/9	UL/cUL
Common Mode Choke (L1)	Astec or Artesyn	Part No. 85272000100 or 801-001965-XXXX	130°C, Consists of (OBMW2), copper magnet wire wound toroidal ferrite core and bobbin, (QMFZ2), Chang Chun Plastic, type T375J, V-0, min. 0.79 mm thick. Secured on PWB by soldering.	-	-
Alternate-Common Mode Choke (L1)	Astec or Artesyn	Part No. 85272000380	130°C, Consists of (OBMW2), copper magnet wire wound toroidal ferrite core and bobbin, (QMFZ2), Chang Chun Plastic, type T375J, V-0, min. 0.79 mm thick. Secured on PWB by soldering.	-	-
Output Choke (L2)	Astec or Artesyn	Part No. 85220101330 or 801-004191-XXXX	130°C, Secondary location. Enameled copper wire wound on cylindrical ferrite core.	-	-
Common Mode Choke (L3)	Astec or Artesyn	Part No. 85272000110 or 801-001966-XXXX	130°C, Consists of (OBMW2), copper magnet wire wound toroidal ferrite core and stand-base, (QMFZ2), Chang Chun Plastic, type T375J, V-0, min.0.79 mm thick. Secured on PWB by soldering.	-	-
Alternate-Common Mode Choke (L3)	Astec or Artesyn	Part No. 85272000090	130°C, Consists of (OBMW2), copper magnet wire wound toroidal ferrite core and stand-base, (QMFZ2), Chang Chun Plastic, type T375J, V-0, min.0.79 mm thick. Secured on PWB by soldering.	-	-
Primary heat sink (Q5)	Interchangeable	Interchangeable	Metal, L-shaped, overall approximately 55.5 by 8.5 mm by 20.5 mm, 1.0 mm thick	-	-
Secondary heat sink	Interchangeable	Interchangeable	Metal, L-shaped, overall approximately 65.0 mm	-	-

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN /Standard	Marks of Conformity
(D2)			by 32.5 by 22.0 by 32.5 mm., 1.0 mm thick.		

Enclosures

Type	Supplement Id	Description
Photographs	Fig.3-01	Overall View 01
Photographs	Fig.3-02	Bottom View
Photographs	Fig.3-03	Overall View 02 (Label shown)
Diagrams	ILL.4-01	T1 Spec
Diagrams	ILL.4-02	L1 Spec
Diagrams	ILL.4-03	L2 Spec
Diagrams	ILL.4-04	L3 Spec
Diagrams	ILL.4-05	L1 Spec (852-7200380)
Diagrams	ILL.4-06	L3 Spec (852-7200090)
Schematics+PWB	ILL.5-01	PCB layout of main board
Manuals	ILL.6-01	Operating Instruction
Miscellaneous	ILL.7-01	Label Artwork
Miscellaneous	ILL.7-02	Client Declaration