CERTIFICATE OF COMPLIANCE

Certificate Number	E146893
Report Reference	E146893-20111006
Issue Date	2020-JUNE-29
Issued to:	XP POWER L L C 15641 RED HILL AVE, SUITE 100 TUSTIN, CA 92780 USA
This certificate confirms that representative samples of	Component - Power Supplies, Medical and Dental Switching Power Supply – Models: ECS45US05, ECS45USXX and ECS25USXX (where XX can be any number between 12 and 48 designating the output voltage, may also be follow by suffix SF or -C or both). Have been investigated by UL in accordance with the component requirements in the Standard(s) indicated on this Certificate. UL Recognized components are incomplete in certain constructional features or restricted in performance capabilities and are intended for installation in complete equipment submitted for investigation to UL LLC.
Standard(s) for Safety:	ANSI/AAMI ES 60601-1:2005 & CSA C22.2 No. 60601-1:08 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance.
Additional Information:	See the UL Online Certifications Directory at https://iq.ulprospector.com for additional information.

This *Certificate of Compliance* does not provide authorization to apply the UL Recognized Component Mark. Only the UL Follow-Up Services Procedure provides authorization to apply the UL Mark.

Only those products bearing the UL Recognized Component Mark should be considered as being UL Certified and covered under UL's Follow-Up Services.

Look for the UL Recognized Component Mark on the product.

Bruce Mahrenholz, Director North American Certification Program

UL LLC

UL TEST REPORT AND PROCEDURE

Standard:	ANSI/AAMI ES 60601-1:2005 (Medical electrical equipment – Part 1: General requirements for basic safety and essential performance) CSA C22.2 No. 60601-1:08 (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:	ECS45US05, ECS45USXX and ECS25USXX (where XX can be any number between 12 and 48 designating the output voltage, may also be follow by suffix SF or -C or both).
Rating:	Input Rating: Model ECS45US05 and Model ECS45USXX Series: 100-240 Vac, 0.9 A, 50/60 Hz Model ECS25USXX Series: 100-240 Vac, 0.6 A, 50/60 Hz Output Rating: All Series: See Model Differences for details.
Applicant Name and Address:	XP POWER LLC SUITE 150 1241 E DYER RD SANTA ANA CA 92705 UNITED STATES

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 Underwriters Laboratories Inc. ('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 Underwriters Laboratories Inc. (UL) or any authorized licensee of UL.

Prepared by: Bermadette Matsuoka
Underwriters Laboratories Inc.

Reviewed by: Melissa DeGuia
Underwriters Laboratories Inc.

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

Products are component power supplies intended to be used as part of Medical Electrical Equipment. It is an open frame power supply intended for building-in Class I or Class II end-products. Double insulated symbol is optionally provided. Earthing symbol may only be provided for Class I power supplies.

Model Differences

All models in the Model ECS45USXX series are identical with exception to the Mains Transformer, T1, and minor secondary components that allow for different output voltage ratings. See below for Model Ratings Table Below for 50°C:

Model ECS45US05: Output Rated: 4.1 Vdc to 6 Vdc, 6.0 A Max (30 W Max)
Model ECS45US12: Output Rated: 10.1 Vdc to 13.5 Vdc, 3.75 A Max (45 W Max)
Model ECS45US15: Output Rated: 13.6 Vdc to 17 Vdc, 3.00 A Max (45 W Max)
Model ECS45US18: Output Rated: 17.1 Vdc to 21 Vdc, 2.5 A Max (45 W Max)
Model ECS45US24: Output Rated: 21.1 Vdc to 26 Vdc Vdc, 1.90 A Max (45 W Max)
Model ECS45US28: Output Rated: 26.1 Vdc to 31 Vdc, 1.61 A Max (45 W Max)
Model ECS45US33: Output Rated: 31.1 Vdc to 33 Vdc, 1.36 A Max (45 W Max)
Model ECS45US36: Output Rated: 33.1 Vdc to 42 Vdc, 1.25 A Max (45 W Max)
Model ECS45US48: Output Rated: 42.1 Vdc to 54 Vdc, 0.95 A (45 W Max)

All respective models in the Model ECS25USXX Series are identical Model ECS45USXX Series, except for the lower output power rating and the heatsink is not provided. See below for Model Ratings Table Below for 50°C:

Model ECS25US12: Output Rated: 10.1 Vdc to 13.5 Vdc, 2.08 A Max (25 W Max)
Model ECS25US15: Output Rated: 13.6 Vdc to 17 Vdc, 1.67 A Max (25 W Max)
Model ECS25US18: Output Rated: 17.1 Vdc to 21 Vdc, 1.39 A Max (25W Max)
Model ECS25US24: Output Rated: 2101 Vdc to 26 Vdc, 1.04 A Max (25 W Max)
Model ECS25US28: Output Rated: 26.1 Vdc to 31 Vdc, 0.89 A Max (25 W Max)
Model ECS25US33: Output Rated: 31.1 Vdc to 33 Vdc, 0.76 A Max (25 W Max)
Model ECS25US36: Output Rated: 33.1 Vdc to 42 Vdc, 0.69 A Max (25 W Max)
Model ECS25US48: Output Rated: 42.1 Vdc to 54 Vdc, 0.52 A Max (25W Max)
See Enclosure - Miscellaneous for de-rated output values for higher ambients.

Suffix "SF" indicates units provided with a single fuse provided in the line side of the primary.

Technical Considerations

- The product was investigated to the following additional standards: ANSI/AAMI ES60601-1:2005/C1:2009**+A1(2012)** (includes National Differences for USA); CAN/CSA-C22.2 No. 60601-1:08**+A1:2014** (includes National Differences for Canada), EN 60601-1:2006**+A1(2013) and IEC 60601-1, Edition 3.1(2012)**
- Scope of Power Supply evaluation defers the following clauses to the be determined as part of the end product:
  Clause 7.5 (Safety Signs),
  Clause 7.9 (Accompanying Documents),
  Clause 9 (ME Hazard),
  Clause 10 (Radiation),
  Clause 14 (PEMS),
  Clause 16 (ME Systems)
- Scope of Power Supply evaluation excludes the following:
  Patient applied parts clauses: 4.6, 7.2.10, 8.3, 8.5.2, 8.5.5, 8.7.4.7-8.7.4.9, 8.9.1.15
  Battery related clauses: 7.3.3, 15.4.3
  Hand Control related clauses: 8.10.4
  Oxygen related clauses: 11.2.2
  Fluids related clauses: 11.6.2 – 11.6.4
  Sterilization clause: 11.6.7
  Biocompatibility Clause: 11.7 (ISO 10993)
  Motor related clauses: 13.2.13.3, 13.4
  Heating Elements related clause: 13.2
  Flammable Anaesthetic Mixtures Protection: Annex G
- The product is Classified only to the following hazards: Casualty, Fire, Shock
- The degree of protection against harmful ingress of water is: Ordinary
- The mode of operation is: Continuous
- Software is relied upon for meeting safety requirements related to mechanical, fire and shock: No
- The product is suitable for use in the presence of a flammable anaesthetics mixture with air or oxygen or with nitrous oxide: No
- Manufacturer's Recommended Ambient: 50°C (See De-rating Curve, Enclosure 7-01 and Enclosure 7-02 for details)
- Classification of installation and use: Building-in
- Supply connection: Building-in
- Accessories and detachable parts included in the evaluation: None
- Options included: None

Risk Controls/Engineering Conditions of Acceptability

For use only in or with complete equipment where the acceptability of the combination is determined by Underwriters Laboratories Inc. When installed in an end-product, consideration must be given to the following:

- Considerations to the applied parts requirements shall be considered as part of the end-product evaluation.
- The end-product evaluation shall ensure that the requirements related to Accompanying Documents, Clause 7.9 are met.
- Consideration should be given to measuring the temperature on power electronic components and transformer windings when the power supply is installed in the end-use equipment. The end-use product shall ensure that the power supply is used within its ratings.
- The output circuits have not been evaluated for direct patient connection (Type B, BF or CF).
- The available voltage for the secondary outputs does not exceed 25 Vac or 60 Vdc, under normal and single fault conditions.
- The input/output connectors are not acceptable for field connections, they are only intended for connection to mating connectors of internal wiring inside the end-use machine.
- Heatsink 1 was considered floating live and should not be connected to earth in the end-product.
- The power supply should be mounted on insulating posts when installed in a Class II end product.
- The "floating" mounting hole shall be mounted on insulating post or properly earthed for Class I end-product.
- Units may be provided with one fuse in the Line side or one fuse in both the Line and Neutral sides. The need for additional fusing shall be determined as part of the end-product evaluation.
- Units provided with either a Cover or Chassis should be used only in a Class I application. The cover and chassis shall be reliably earthed in the end-use application.
- When installed in a Class I end product, the power supply shall be mounted in a manner that provides, at a min. 2.5 mm Clearance between the primary side of the power supply and protectively earthed accessible conductive parts. In addition, when installed in a Class I end product, the protective bonding terminal of the power supply shall be reliably connected to the main protective earthing terminal of the end product.
- When installed in a Class II end product, the power supply shall be mounted, on insulating posts, in a manner that provides, at a min. 5 mm Clearance between the primary side of the power supply and any accessible conductive parts.
- Power supply provides the following MOPP (means of patient protection): two MOPP based upon a working voltage 240 Vrms, 531 Vpk between Primary to Secondary, one MOPP based upon a working voltage 250 Vrms, 354 Vpk between Primary and Earth/Enclosure
- Temperature, Leakage Current, Protective Earthing, Dielectric Voltage Withstand, and Interruption of the Power Supply tests should be considered as part of the end product evaluation.
- The product was submitted and evaluated for use at the maximum ambient temperature (Tmra) permitted by the manufacturer's specification of: 50°C (See De-rating Curve, Enclosure 7-01 and Enclosure 7-02 for details)
- Magnetic devices T1 employs a Class F (155°C) insulation system. Magnetic devices L1, L2, L3 employ a Class F (155°C insulation system
- The PWB is rated 130°C.
- The products were tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.
- The need for marking durability testing to be considered as part of the end product application.
- The power supplies have been evaluated as continuous operation and have not been evaluated for use in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.
- A single maximum current rating of 0.9A or 0.6A were provided for the entire 100-240Vac voltage range. The end product evaluation shall consider the acceptability of this component power supply rating as it relates to the requirements of Clause 7.2.7.

Additional Information

The clearance distances have additionally been assessed for suitability up to 3000 m elevation. The creepage and clearance measurement in Table: To insulation diagram are derived from 2nd edition evaluation.

The need for the additional testing and evaluation shall be determined in the end product investigation.

Models covered under this Report have been additionally evaluated to AAMI ES60601-1:2005 (R2012), CSA CAN/CSA-C22.2 No. 60601-1:14 and IEC 60601-1 Edition 3.1 (2012)

Markings and instructions

Clause Title	Marking or Instruction Details
Company identification	Classified or Recognized company's name, Trade name, Trademark or File
Model	Model number
Alternating current	
Supply Connection	Voltage range, ac/dc, phases if more than single phase
Direct current	
Power Input	Amps, VA, or Watts
Output	Rated output voltage, power, frequency.
Funtional Earth Terminal	
Serial Number or lot or batch identifier	**Eight alpha numeric characters (A BB CC DDD where A = factory code; BB = year; CC=week; DDD = serial number)**
Date of Manufacturer	**Provided as part of the serial number**

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
All Models	Test	Test	Exempt

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:

N/A

Sample and Test Specifics for Follow-Up Tests at UL

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

Model	Samples	Test	Test Details
N/A			