# CERTIFICATE OF COMPLIANCE

 Certificate Number
 2015-10-29-E321744

 Report Reference
 E321744-D1002-1-ULCB

Issue Date 2015-10-29

**Issued to:** XP Power LLC

Applicant Company: 15641 Red Hill Ave., Suite 100

Tustin, CA 92780 USA

Listed Company: Same as Applicant

This is to certify that Component Power Supply intended for Building-in

representative samples of EPL225PSXX (where XX can be any number between 12 and 48 designating the output voltage, may also be provided with

suffix "SF"

Have been investigated by UL in accordance with the

Standard(s) indicated on this Certificate.

Standard(s) for Safety: ANSI/AAMI ES60601-1:2005/(R)2012, CSA CAN/CSA-C22.2

NO. 60601-1:14, IEC 60601-1 Edition 3.1 (2012)

Additional Information: See the UL Online Certifications Directory at

www.ul.com/database for additional information.

Only those products bearing the UL Certification Mark should be considered as being covered by UL's Certification and Follow-Up Service.

Recognized components are incomplete in certain constructional features or restricted in performance capabilities and are intended for use as components of complete equipment submitted for investigation rather than for direct separate installation in the field. The final acceptance of the component is dependent upon its installation and use in complete equipment submitted to UL LLC.

Look for the UL Certification Mark on the product.

This is to certify that representative samples of the product as specified on this certificate were tested according to the current UL requirements.

Barrelly Jane

Helena J. Wolf,
Helena Y. Wolf, Director, Global Market Access Operations.

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# Description

# **UL TEST REPORT AND PROCEDURE**

Standard: ANSI/AAMI ES60601-1:2005/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14, IEC 60601-1 Edition 3.1 (2012) **Certification Type:** Component Recognition CCN: QQHM2 / QQHM8 **Complementary CCNs:** Product: Component Power Supply intended for Building-in EPL225PSXX (where XX can be any number between 12 and 48 Model: designating the output voltage, may also be provided with suffix "SF" Rating: Input: 100-240 Vac, 50/60Hz, 3A Max.; Output: See Model Differences for details **Applicant Name and** XP Power LLC 15641 Red Hill Ave., Suite 100 Address: Tustin, CA 92780, USA

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 as applicable.

Any information and documentation involving UL Mark services are provided on behalf of UL LLC (UL) or any authorized licensee of UL.

Prepared by: Melissa DeGuia Reviewed by: Timothy L. Gambrell

### **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**

The models covered in this report are component AC-DC power supplies intended for use in Medical Equipment. They are open frame power supplies intended for building-in.

Refer to the Report Modifications page for any modifications made to this report.

#### **Model Differences**

All models in the Model EPL225PSXX Series are identical with exception to the Mains Transformer (TR1) and minor secondary components that allow for different output voltage ratings.

Suffix "-SF" indicates signle fuse provided in the line side of the primary.

#### Output Ratings:

EPL225PS12: V1: 10.1-13.5Vdc, 12.5A Max., 150 W Max. (Convection Cooled) or 10.1-13.5Vdc, 18.75A Max., 225 W Max. (Forced Air Cooled); V2: 12Vdc, 0.5A, (Forced Air Cooled Only)

EPL225PS15: V1: 13.6-17Vdc, 10A Max., 150 W Max. (Convection Cooled) or 13.6-17Vdc, 15A Max., 225 W Max. (Forced Air Cooled): V2: 12Vdc. 0.5A. (Forced Air Cooled Only)

EPL225PS18: V1: 17.1-21Vdc, 8.33A Max., 150 W Max. (Convection Cooled) or 17.1-21Vdc, 12.5A Max., 225 W Max. (Forced Air Cooled); V2: 12Vdc, 0.5A, (Forced Air Cooled Only)

EPL225PS24: V1: 21.1-26Vdc, 6.25A Max., 150 W Max. (Convection Cooled) or 21.1-26Vdc, 9.38A Max., 225 W Max. (Forced Air Cooled); V2: 12Vdc, 0.5A, (Forced Air Cooled Only)

EPL225PS28: V1: 26.1-31Vdc, 5.36A Max., 150 W Max. (Convection Cooled) or 26.1-31Vdc, 8.04A Max., 225 W Max. (Forced Air Cooled); V2: 12Vdc, 0.5A, (Forced Air Cooled Only)

EPL225PS33: V1: 31.1-33Vdc, 4.54A Max., 150 W Max. (Convection Cooled) or 31.1-33Vdc, 6.81A Max., 225 W Max. (Forced Air Cooled); V2: 12Vdc, 0.5A, (Forced Air Cooled Only)

EPL225PS36: V1: 33.1-42Vdc, 4.16A Max., 150 W Max. (Convection Cooled) or 33.1-42Vdc, 6.25A Max., 225 W Max. (Forced Air Cooled); V2: 12Vdc, 0.5A, (Forced Air Cooled Only)

EPL225PS48: V1: 42.1-54Vdc, 3.1A Max., 150 W Max. (Convection Cooled) or 42.1-54Vdc, 4.69A Max., 225 W Max. (Forced Air Cooled); V2: 12Vdc, 0.5A, (Forced Air Cooled Only)

## **Additional Information**

The required clearance values have been assessed for suitability up to 4000 m elevation (1.14 correction factor as per IEC 60664-1, Table A2).

The need for the additional testing and evaluation shall be determined in the end product investigation. The nameplate markings provided as an Enclosure - Marking Plate are considered representative of the entire series.

The power supply series covered by this report employ Double/Reinforced Insulation between Primary and Secondary circuits.

#### **Technical Considerations**

- The product was investigated to the following additional standards: None
- The following additional investigations were conducted: N/A

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- 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 following accessories were investigated for use with the product: None
- 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
- The product is evaluated only to the following hazards: Casualty, Fire, Shock
- The degree of protection against harmful ingress of water is: Ordinary
- Software is relied upon for meeting safety requirements related to mechanical, fire and shock: No
- The product was submitted and evaluated for use at the maximum ambient temperature (Tma) permitted by the manufacturer's specification of: 50°C at full rated load and 70°C at 50% rated load. See the Output Ratings Table in the Model Differences section for details.

# **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 end-product Electric Strength Test is to be based upon a maximum working voltage of: Primary-Secondary: 280 Vrms, 484 Vpk, Primary-Earthed Dead Metal: 240 Vrms, 400 Vpk
- The power supply terminals and/or connectors are: Not investigated for field wiring
- The maximum investigated branch circuit rating is: 20A
- Proper bonding to the end-product main protective earthing termination is: Required
- An investigation of the protective bonding terminals has: Not been conducted
- The following input terminals/connectors must be connected to the end-product supply neutral: Input Connector (CN1) N terminal.
- The following magnetic devices (e.g. transformers or inductor) are provided with an OBJY2 insulation system with the indicated rating greater than Class A (105°C): TR1 (Class F)
- The following end-product enclosures are required: Fire, Mechanical, Electrical
- Suitable disconnect device is to be provided in the end system.
- Temperature, Leakage Current with a non-frequency weighted device and Dielectric Strength testing shall be considered in the end system.
- Printed Wiring Board rated 130°C.
- Heatsinks are floating and considered live. They should not be accessible in the end-product.
- Heating test was not conducted on unit with input/output leads. If unit is provided with input and/or output leads, then temperature on leads must be measured and cannot exceed 105°C.

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- This power supply has been evaluated as a 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. The
- output circuits have not been evaluated for direct patient connection (Type B, BF or CF).

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 The end product shall ensure that the requirements related to accompanying documents, clause 7.9, are met.

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 The need for Marking Durability and Marking Legibility Testing shall be considered as part of the end product installation.

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 Models provided with suffix SF only provided with one line side fuse. Consideration should be made in the end-use product to determine the need of double pole fusing.

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The suitability of the breaking capacity of the fuse per Clause 8.11.5 shall be verified in the end product.

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When installed in a Class II end product, the power supply shall be mounted in a manner that provides sufficient clearance and creepage distance between the hazardous parts and accessible conductive parts.

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- Proper bonding to the Class I end-product main protective earthing termination is required (via mounting holes on the PCB), unless for Class II applications. For Class II applications the primary side mounting
- pads are isolated from accessible conductive chassis by Reinforced Insulation.

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 This power supply was evaluated with Two MOPP between Primary and Secondary for 484Vpk/280Vrms: One MOPP between primary and Earth for 400Vpk/240Vrms.