CERTIFICATE OF COMPLIANCE

Certificate Number 2018-05-08; 2018-07-11 (A1)-E146893

Report Reference E146893-D1024-1/A1/C0-ULCB **Issue Date** 2018-05-08; 2018-07-11 (A1)

> Issued to: XP POWER LLC

Applicant Company: 15641 Red Hill Ave., Ste. 100

Tustin, CA 97280 USA

Same as Applicant **Listed Company:**

Component switching power supply for use in Medical Electrical This is to certify that

representative samples of Equipment

> CMP250PSXX-YY, where XX is 24-48, YY is "SF" or blank, may also be provided with additional suffixes "-C", and "-S", all "-"

considered optional.

Have been investigated by UL in accordance with the

Standard(s) indicated on this Certificate.

Standard(s) for Safety: ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and

A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14, IEC

60601-1 Edition 3.1 (2012)

Additional Standards: EN 60601-1:2006 / A1:2013 / A12:2014, IEC 60601-1: 2012, 3rd

Edition with Am. 1

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. 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.

Bruce Mahrenholz, Assistant Chief Engineer, Global Inspection and Field Services, UL LLC

Joseph Hosey, General Manager, Director of Sales – Canada, UNDERWRITERS LABORATORIES OF CANADA INC.



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Description

UL TEST REPORT AND PROCEDURE

Standard: ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(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 switching power supply for use in Medical Electrical Equipment Model: CMP250PSXX-YY, where XX is 24-48, YY is "SF" or blank, may also be provided with additional suffixes "-C", and "-S", all "-" considered optional. Rating: Input: 100-240Vac, 50/60Hz, 3.8A max. Output: See Model Differences for details (ranges from 42.1Vdc , 5.2A to 21.1Vdc, 10.4 A) **Applicant Name and** XP POWER LLC Address: 15641 Red Hill Ave., Ste. 100 Tustin, CA 97280, 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.

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Prepared by: Rahul Baria, Project Reviewed by: Ahmad Daoudi, Project

Handler Reviewed by. Reviewer

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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 product is a component AC-DC power supply for building-in, open frame type provided with a metal chassis, incorporating primary and SELV components.

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

Model Differences

All models within the series are identical with exception to the output rating, mains transformer windings, and minor secondary components.

Models CMP250PSXX-YY have the following nomenclature:

XX = 24-48, denotes the rated output voltage.

YY = SF or blank, denotes either single pole fusing (SF) or double fusing (blank)

Units provided with additional suffix "-C" provided with Cover.

Units provided with additional suffix "-S" indicates models provided with input screw terminals.

See below for the Output Rating for 50°C Ambient provided with Forced Air Cooling. See De-rating Curve, Misc. Enclosure 10-002, for 70°C Ambient loading.

Model CMP250PS24XX-YY: 21.1 Vdc to 26 Vdc, 10.4 A Max, (250 W Max, Convection Cooling or Forced-Air Cooling or Covered with Forced Air Cooling)(206 W Max, Covered Convection Cooling)

Model CMP250PS28XX-YY: 26.1 Vdc to 31 Vdc, 9.0 A Max, (250 W Max, Convection Cooling or Forced-Air Cooling or Covered with Forced Air Cooling)(206 W Max, Covered Convection Cooling)

Model CMP250PS33XX-YY: 31.1 Vdc to 33 Vdc, 7.6 A Max, (250 W Max, Convection Cooling or Forced-Air Cooling or Covered with Forced Air Cooling)(206 W Max, Covered Convection Cooling)

Model CMP250PS36XX-YY: 33.1 Vdc to 42 Vdc, 6.9 A Max, (250 W Max, Convection Cooling or Forced-Air Cooling or Covered with Forced Air Cooling)(206 W Max, Covered Convection Cooling)

Model CMP250PS48XX-YY: 42.1 Vdc to 54 Vdc, 5.2 A Max, (250 W Max, Convection Cooling or Forced-Air Cooling or Covered with Forced Air Cooling)(203 W Max, Covered Convection Cooling)

Stand-by Output for all models: 5Vdc,1.5 A Max, de-rated by percentage same as conditions noted above for main output.

Additional Information

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Marking label is representative of all models.

Licenses older than 3 years to be provided by the manufacturer upon request.

The required clearance values have been assessed for suitability up to 5000 m elevation for Patient Protection (MOPP) (1.29 correction factor as per Table 8).

The models covered under this Report have been additionally evaluated to EN 60601-1:2006 / A1:2013 / A12:2014. Additional evaluation into EN 60601-1/A11:2011/A12:2014 was considered and deemed not applicable for the devices covered under this Report as they are component power supplies.

Technical Considerations

- The product was investigated to the following additional standards: EN 60601-1:2006 / A1:2013 / A12:2014, IEC 60601-1: 2012, 3rd Edition with Am. 1
- The following additional investigations were conducted: N/A
- The product was not investigated to the following standards or clauses: Biocompatibility, PESS, EMC, Annex Z of EN standards for compliance with the MDD
- The following accessories were investigated for use with the product: N/A
- 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 power supply was evaluated for use in 50°C ambient at Full Rated Output and 50% of the Rated Output in 70°C ambient.

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:

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- The component shall be considered for compliance with the Marking (clause 7) and Separation (clause 8) requirements as part of the end use application evaluation.
- The power supply was evaluated for use in 50°C ambient at Full Rated Output and 50% of the Rated Output in 70°C ambient.
- Consideration shall 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. Repeat of leakage current testing and consideration of non-frequency weighted leakage test shall be considered in the end product application.
- This power supply was evaluated with Two MOPP between Primary and Secondary; One MOPP primary and Earth. One MOPP based upon a working voltage 240 Vrms between secondary and earthing trace or chassis for BF output consideration.

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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).

- The end product shall ensure that the requirements related to accompanying documents, clause 7.9, are met
- The available voltage for the secondary outputs does not exceed 42.4 Vac peak or 60 Vdc, under normal and single fault conditions.
- The output connectors are suitable for factory wiring only.
- The maximum investigated branch circuit rating is: 20 A
- The Electric Strength Test conducted on this power supply was based upon a maximum working voltage of: Primary-Earthed Dead Metal: 240 Vrms, 344 Vpk; Primary-SEC: 240 Vrms, 492 Vpk.
- Proper bonding to the end-product main protective earthing termination is required. Protective earthing testing shall be conducted in the end product application.
- 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): T1, T2, T3, T4 (Class F, 155°C)
- Printed Wiring Board rated 130°C
- The need for Marking Durability and Marking Legibility Testing shall be considered as part of the end product installation.
- Fire/ Mechanical/ Electrical Enclosure to be provided as part of the end product.
- 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.
- 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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