CERTIFICATE OF COMPLIANCE

Certificate Number 2018-09-28 (A0/C0)-E321744

Report Reference E321744-D1018-1/A0/C0-ULCB

Issue Date 2018-09-28 (A0/C0)

Issued to: XP POWER L L C

Applicant Company: 15641 RED HILL AVE, SUITE 100

TUSTIN CA 92780 USA

Listed Company: Same as Applicant

This is to certify that Component DC-to-DC Converter

representative samples of IMM05xxSyyy and IMM05xxDyyy (where xx is 05, 12, or 24

representing input voltage; yyy is 3V3, 05, 12 or 15 representing

output voltage)

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:

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 Shithour

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

Helena Y. Wolf, Director, Global Market Access Operations, UL LLC

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

<u>(UL)</u>

Any information and documentation involving UL Mark services are provided on behalf of UL LLC (UL) or any authorized licensee of UL. For questions, please contact a local U

Page C-29 of C-36 F

Report No.: E321744-D1018-1/A0/C0-

ULCB

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:** QQHM8 Product: Component DC-to-DC Converter Model: IMM05xxSyyy and IMM05xxDyyy (where xx is 05, 12, or 24 representing input voltage; yyy is 3V3, 05, 12 or 15 representing output voltage) Rating: 4.5 Vdc to 9 Vdc, 9Vdc to 18Vdc, or 18Vdc to 36Vdc corresponding to input markings of 5 Vdc, 12 Vdc, or 24 Vdc respectively **Applicant Name and** XP POWER L L C Address: 15641 RED HILL AVE, SUITE 100 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: Rahul Baria, Project Reviewed by: Ahmad Daoudi, Project

Handler Reviewed by. Reviewer

Page C-30 of C-36 Report No.: E321744-D1018-1/A0/C0-

ULCB

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 unit is a component dc to dc Converter to be used as part of Medical Electrical Equipment, and is intended to provide one MOPP between input circuits to output circuit

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

Model Differences

IMM05xxSyyy and IMM05xxDyyy, where xx is 05, 12, or 24 representing input voltage; and yyy is 3V3, 05, 12, or 15 representing output voltage

Model IMM05xxDyyy Series is identical to Model IMM05xxSyyy Series except it is provided with two outputs instead of one.

All models within a series are identical except for transformer windings, inductance and MOSFETs, and output ratings.

See below for Model Output Ratings @ 60°C.

IMM05XXS3V3: 3.3Vdc, 1200mA IMM05XXS05: 5 Vdc, 1000mA IMM05XXS12: 12Vdc, 416mA IMM05XXS15: 15Vdc, 333mA

IMM05XXD12: +12Vdc, 208mA; -12Vdc, 208mA IMM05XXD15: +15Vdc, 166mA; -15Vdc, 166mA

Where XX can be 05, 12, or 24, and denotes nominal input voltage ranges as follows:

05 = 4.5-9Vdc 12 = 9-18Vdc 24 = 18-36Vdc

Additional Information

Marking label submitted is representative of all models in this Report.

When submitting this Test Report to other Certification Body, the manufacturer is responsible for providing any additional information that the Body may need in order to issue its Mark, including testing for compliance with the applicable collateral standards.

Technical Considerations

- The product was investigated to the following additional standards:
- The following additional investigations were conducted: None
- The product was not investigated to the following standards or clauses: Biocompatibility, EMC, Annex Z of EN standards for compliance with the MDD
- The following accessories were investigated for use with the product: None
- The degree of protection against harmful ingress of water is: Ordinary
- The product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide: No

Page C-31 of C-36 Report No.: E321744-D1018-1/A0/C0-

ULCB

Scope of this 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 16 (ME Systems).
- Scope of this 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.

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 component dc to dc converter has been judged on the basis of the required creepage and clearances for 1 MOPP based on a working voltage of 250Vrms, 354Vpk between input and output circuits at an altitude of 5000m in accordance with Standard for Medical Electrical Equipment, Part 1: General requirements for basic safety and essential performance, ANSI/AAMI ES 60601-1:2005 (R) 2012, CSA C22.2 No. 60601-1:2014 and IEC 60601-1, Edition 3.1, Sub-clause 8.9, which covers the end-use product for which the component was designed
- .
- The unit is a DC/DC converter and not evaluated for the separation to SUPPLY MAINS; suitable MAINS separation shall be provided during final installation
- 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 tested for use at the manufacturer's recommended ambient temperature (Tmra) of 60°C at Full Load
- The output circuit has not been evaluated for connecting to Applied Parts. For end products intended to connect to Applied Parts, suitable evaluation should be considered
- 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 dc-to-dc converter is used within its ratings
- The end-product evaluation shall ensure that the requirements related to Accompanying Documents, Clause 7.9 are met.
- End product Risk Management Process to include consideration of requirements specific to the Power Supply.
- End product Risk Management Process to consider the need for simultaneous fault condition 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 Leakage of Liquids 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 products were tested on a 20 A branch circuit. If used on a branch circuit greater than this,

Page C-32 of C-36 Report No.: E321744-D1018-1/A0/C0-

ULCB

additional testing may be necessary.

The label has not been evaluated, the need to conduct the durability of marking and legibility of marking tests should be determined in the end product.

The product is a component for building in, the accessibility shall be determined as part of the end product investigation.