

CERTIFICATE OF COMPLIANCE

Certificate Number 2018-12-28-E321744
Report Reference E321744-D1021-1/A0/C0-UL
Issue Date 2018-12-28

Issued to: XP Power LLC
Applicant Company: 15641 Red Hill Ave, Suite 100
Tustin, California
92780 USA

Listed Company: Same as Applicant

This is to certify that representative samples of DC-DC Converter
JHM20xyzz (xx is 12 or 24 or 48 representing input voltage; y is S or D representing single or dual output type; ZZ is 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

Additional Standards: N/A

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.


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		
Certification Type:	Component Recognition		
CCN:	QQHM2 / QQHM8		
Complementary CCNs:			
Product:	DC-DC Converter		
Model:	JHM20xyzz (xx is 12 or 24 or 48 representing input voltage; y is S or D representing single or dual output type; ZZ is 05, 12 or 15 representing output voltage)		
Rating:	Model No.	Input Ratings	Output Ratings
	JHM2012S05	9-18Vdc; 3.5A	5Vdc; 4A
	JHM2012S12	9-18Vdc; 3.5A	12Vdc; 1.67A
	JHM2012S15	9-18Vdc; 3.5A	15Vdc; 1.333A
	JHM2012D05	9-18Vdc; 3.5A	±5Vdc; ±2A
	JHM2012D12	9-18Vdc; 3.5A	±12Vdc; ±0.833A
	JHM2012D15	9-18Vdc; 3.5A	±15Vdc; ±0.667A
	JHM2024S05	18-36Vdc; 1.75A	5Vdc; 4A
	JHM2024S12	18-36Vdc; 1.75A	12Vdc; 1.67A
	JHM2024S15	18-36Vdc; 1.75A	15Vdc; 1.333A
	JHM2024D05	18-36Vdc; 1.75A	±5Vdc; ±2A
	JHM2024D12	18-36Vdc; 1.75A	±12Vdc; ±0.833A
	JHM2024D15	18-36Vdc; 1.75A	±15Vdc; ±0.667A
	JHM2048S05	36-75Vdc; 0.85A	5Vdc; 4A
	JHM2048S12	36-75Vdc; 0.85A	12Vdc; 1.67A
	JHM2048S15	36-75Vdc; 0.85A	15Vdc; 1.333A
	JHM2048D05	36-75Vdc; 0.85A	±5Vdc; ±2A
	JHM2048D12	36-75Vdc; 0.85A	±12Vdc; ±0.833A
	JHM2048D15	36-75Vdc; 0.85A	±15Vdc; ±0.667A
Applicant Name and Address:	XP Power LLC 15641 Red Hill Ave, Suite 100 Tustin, California 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: Zhuo Guoping, Project Handler

Reviewed by: Lee Chenchen, Project Reviewer

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 build-in component type DC-DC converter for use in Medical Electrical Equipment. The unit consists of primary and secondary circuits; all components, PWB and transformer are potted in a plastic enclosure.

The product operating temperature is -40 to 80°C; with the maximum operating ambient temperature 60 °C for full load (20W) and 80°C for derating to 50% load (10W).

The product provides 2 MOPP between primary circuitry and secondary circuitry; based on 250Vrms (Manufacturer declaration); and operates within 4000m altitude.

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

Model Differences

The models of the product series JHM20xyzz have different ratings; where xx is 12 or 24 or 48 representing input voltage; y is S or D representing single channel or dual channel output type; ZZ is 05, 12 or 15 representing output voltage. See model ratings for exact rating details. Due to different ratings, the transformer used in the product construction is different. Refer to Enclosure – Diagrams (3) for transformer specifications used for respective product model.

The difference between single channel output and dual channel output is on secondary circuit and not affecting primary circuit.

Additional Information

Project 4788682112 (Dec'2018)

Conversion of CB report (CB 269692-70191158) issued by CSA South Korea; to UL, cUL report

Technical Considerations

- The product was investigated to the following additional standards: N/A
- 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
- N/A

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 product has been evaluated on the basis of the required Creepage and Clearance according to Clause 8.9 in the ANSI/AAMI ES60601-1 (2005/(R)2012 + A1:2012, C1:2009/(R)2012 + A2:2010/(R)2012), CAN/CSA-C22.2 No. 60601-1:14 that cover the end application for which the component was designed. The clearance requirement product was evaluated for compliance using 4,000m altitude operation and Pollution degree 2.
- The product normal environmental conditions have been evaluated using -40 to 80 deg C, 0 to 95%

RH% non-condensing; and 540 to 1060hPa.

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- The product has been evaluated as a built in DC-DC converter intended to be used with medical power supplies in continuous operation. The evaluation does not cover the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. Additional evaluation is required in the end product for this aspect.
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- The product has not been investigated for the protection against hazards of explosions in medically used rooms.
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- Scope of DC-DC converter evaluations excludes the following clauses and they should be re-evaluated during end product configuration certification:
 - Clause 7.5 (Safety Signs),
 - • Clause 7.9 (Accompanying Documents),
 - • Clause 9 (ME Hazard), except 9.1 and 9.3 are evaluated,
 - • Clause 10 (Radiation),
 - • Clause 14 (PEMS),
 - • Clause 16 (ME Systems)
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- The end configuration product should provide proper installation and operation instructions in the accompanying documents or technical description documents; and these should include Input/Output ratings and maximum operation ambient conditions. Installation instructions and equipment markings related to safety will be in a language acceptable in the country in which the equipment is to be installed
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- The product is not intended to be field serviced or repaired; and shall be installed in compliance with proper enclosure, mounting with adequate clearances and creepages. Insulation is to be re-evaluated during end product configuration.
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- The product is to be installed with stable power source as the 90% and 110% input voltage were not considered during evaluation.
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- Disconnecting device is to be provided in end product configuration.
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- Considerations to the applied parts requirement shall be evaluated in the end-product. The output circuits have not been evaluated for direct patient connection (Type B, BF or CF).
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- The electrical, fire and mechanical enclosure requirements of the Standard are to be considered at end product evaluation as the product has been evaluated as a build-in component.
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- The product was evaluated with 2 MOPP (Means of Patient Protection) based upon manufacturer declaration of 250Vrms working voltage; between Primary to Secondary circuit. The core of the Transformer (T101) was evaluated as secondary circuit. The product is evaluated as a build-in component and the plastic enclosure not requiring insulation. Evaluation was done at operating ambient of 60 deg C and 80 deg C.
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- Maximum working voltages between primary and secondary were measured: 101Vrms; 158Vpk.
- The product output have energy < 240VA according to Clause 8.4.2c.
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- The product was evaluated using 20A as branch circuit protection. Additional evaluation is required if it is used on branch circuit with greater protection.

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- The insulation system classification of the transformer (T101) is Class B.
- The following tests shall be performed in end-product evaluation: Temperature test, Dielectric Voltage Withstand test and Leakage current test
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- The end-product evaluation shall ensure that the requirements related to Marking (Clause 7.2) and Accompanying Documents (Clause 7.9) are met; and should address any patient connection (Applied Parts) application.
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- The accessibility of output connectors, insulating materials and temperatures shall be re-evaluated in the end product.
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- Interruption of Power Supply (Clause 11.8) shall be considered in the end product evaluation if applicable.

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
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.

Special Instructions to UL Representative
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Production-Line Testing Requirements		
<u>Test Exemptions</u> - The following models are exempt from the indicated test		
Test	Exemption Specifics	Details
Grounding Continuity	The following models are exempt from the indicated test:	All models are exempted
Dielectric Voltage Withstand	The following models are exempt from the indicated test:	All models are not exempted
Patient Circuit Dielectric Voltage Withstand	The following models are exempt from the indicated test:	N/A; all models are exempted
Solid-State Components	The following solid-state components may be disconnected from the remainder of the circuitry during either Dielectric Voltage Withstand Test:	N/A; all models are exempted

<u>Sample and Test Specifics for Follow-Up Tests at UL</u>			
The following tests shall be conducted in accordance with the Generic Inspection Instructions			
Plastic Enclosure or Part	Test	Sample(s)	Test Specifics
None	NA	NA	NA
