

# CERTIFICATE OF COMPLIANCE

**Certificate Number** 2016-10-20-E321744  
**Report Reference** E321744-D1014-1/A0/C0-ULCB  
**Issue Date** 2016-10-20  
**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  
representative samples of**

Component Power Supply DC-to-DC Converter  
IMA01xxSyyy and IMA01xxDyyy (where xx is 05, 12, 15 or 24  
representing input voltage; yyy is 03, 3V3, 05, 09, 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:**

None

**Additional Information:**

See the UL Online Certifications Directory at  
[www.ul.com/database](http://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.

*B. Mahlenholz*

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

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Customer Service Representative [www.ul.com/contactus](http://www.ul.com/contactus)



**Description****UL TEST REPORT AND PROCEDURE**

<b>Standard:</b>	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)
<b>Certification Type:</b>	Component Recognition
<b>CCN:</b>	QQHM2 / QQHM8
<b>Complementary CCNs:</b>	
<b>Product:</b>	Component Power Supply DC-to-DC Converter
<b>Model:</b>	IMA01xxSyyy and IMA01xxDyyy (where xx is 05, 12, 15 or 24 representing input voltage; yyy is 03, 3V3, 05, 09, 12 or 15 representing output voltage)
<b>Rating:</b>	Input: 4.5-5.5VDC, 10.8-13.2VDC, 13.5-16.5VDC, 21.6-26.4VDC. See GPI model differences for output ratings.
<b>Applicant Name and Address:</b>	XP POWER L L C 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: Haydee Gonzalez

Reviewed by: Haroon Samadi

**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**

IMA01xxSyyy and IMA01xxDyyy, where xx is 05, 12, 15 or 24 representing input voltage; and yyy is 03 or 3V3, 05, 09, 12 or 15 representing output voltage). Model IMA01xxDyyy Series is identical to Model IMA01xxSyyy 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.

Where XX can be 05, 12, 15 or 24 and denotes nominal input voltage ranges as follows:

05 = 4.5 - 5.5VDC

12 = 10. 8 - 1 3.2VDC

15 = 13. 5 - 16.5VDC

24 = 21.6 - 26.4VDC

See below for Model Output Ratings @ 85°C.

IMA01xxS3V3: 3.3VDC 300mA

IMA01xxD03: ±3.3VDC 150mA

IMA01xxS05: 5 VDC 200mA

IMA01xxD05: ±5VDC 100mA

IMA01xxS09: 9VDC 111mA

IMA01xxD09: ±9 VDC 55.5mA

IMA01xxS12: 12VDC 83.3mA

IMA01xxD12: ±12VDC 41.6mA

IMA01xxS15: 15VDC 66.7mA

IMA01xxD15: ±15VDC 33.3mA

**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: None
- The following additional investigations were conducted: None
- 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: 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
- Scope of this evaluation defers the following clauses to the be determined as part of the end product: Clause 4.2 Risk Management, Clause 4.3 (Essential Performance), Clause 4.4 (Expected Service Life), 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 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 75°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, 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.

- • Potting compound not evaluated as an isolation barrier.
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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
Serial number or lot or batch identifier	Serial number or lot or batch identifier
Date of manufacture or use by date	Date of manufacture or use by date
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**

None

**Production-Line Testing Requirements****Test Exemptions** - The following models are exempt from the indicated test

Test	Exemption Specifics	Details
Grounding Continuity	The following models are exempt from the indicated test:	Exempt
Dielectric Voltage Withstand	The following models are exempt from the indicated test:	Not Exempt
Patient Circuit Dielectric Voltage Withstand	The following models are exempt from the indicated test:	Exempt
Solid-State Components	The following solid-state components may be disconnected from the remainder of the circuitry during either Dielectric Voltage Withstand Test:	Exempt

**Sample and Test Specifics for Follow-Up Tests at UL**

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

TABLE: List of Critical Components

8.10 <b>TABLE: List of critical components</b>					
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No. <sup>1</sup>	Required Mark(s) & Certificates of Conformity
Enclosure	Wah Hong	WH-9100	Rated V-0, 130°C, min 1.0mm thick	UL 746C, UL 94 (QMF22 (E150608))	UL
PWB	Interchangeable	Interchangeable	Rated V-0, 130C, see Enclosure Schematics + PWB for trace and component layouts	UL 758 (ZPMV2)	UL
Transformer (T1)	-	-	Constructed with the following components, see Misc. Enclosure Diagram for details.	-	-
Transformer (T1)	Sheng Chuan electronics Co., Ltd	B-888	Rated 130°C (Class B insulation system)	UL 1446 (OBJY2, E468816)	UL
Transformer (T1) Core	Interchangeable	Interchangeable	Toroidal, ferrite with overall dimensions approx. 7.6mm OD and 3.4mm ID, 2.5 mm wide		-
Transformer (T1) Primary wire	Interchangeable	Interchangeable	Enameled Copper wire, rated 130degC	UL 1446 (OBMW2)	UL
Transformer (T1) Secondary wire	Rubadue Wire Co Inc	T-AA-X-XX-T-XXX-2 or T-AA-X-XX-T-XXX-1.5 (T32A01TXXX-2 or T32A01TXXX-1.5)	Rated 707V, 155°C, Rated 1000 Vpk, 155°C. (Dielectric Strength of 14kVrms conducted on twisted pair during component evaluation)	UL 2353 (OBJT2 (E206198))	UL
Transformer (T1) Secondary wire - alternate	Furukawa	Tex-E	130°C	UL2353 (OBJT2, E206440)	UL
Potting Compound	Lord Corporation	CK-6009	(Not evaluated/relied upon for MOP) Min V-1, 90°C	UL 94 (QMF22 (E84716)	UL, cUL
Potting Compound - alternate	Interchangeable	Interchangeable	(Not evaluated/relied upon for MOP) Min V-1, min 90°C	UL 94 (QMF22)	UL, cUL
Tape	3M COMPANY ELECTRICAL MARKETS DIV (EMD)	1350F-1	130°C -	UL (E17385)	UL

## Supplementary information:

The Test Laboratory has verified the component information.

- 1) Anything specified within brackets "( )" is for reference purposes only and can be used to specify the UL Product Category CCN(s)/File Number if the component includes a UL Certification. This can be useful for the UL Follow-Up Service Inspection associated with the UL Mark; however if in brackets, should not be a required element of the UL Inspection.

----- END OF APPENDIX C -----



## TEST RESULTS:

### APPENDIX D: Test Datasheets Enclosures

The following tests have been performed as part of this report:

Standard	Clause No.	Test Name	Testing Location / Comments
IEC 60601 1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)	4.11	Power Input	XP Power Limited, 401 Commonwealth Drive, Haw Par Technocentre, Lobby B, #02-02, Singapore 149598
IEC 60601 1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)	5.7	Humidity Conditioning	XP Power Limited, 401 Commonwealth Drive, Haw Par Technocentre, Lobby B, #02-02, Singapore 149598
IEC 60601 1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)	8.5.4	Working Voltage Measurements	XP Power Limited, 401 Commonwealth Drive, Haw Par Technocentre, Lobby B, #02-02, Singapore 149598
IEC 60601 1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)	8.8.3	Dielectric Voltage Withstand	XP Power Limited, 401 Commonwealth Drive, Haw Par Technocentre, Lobby B, #02-02, Singapore 149598
IEC 60601 1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)	8.8.4.1	Ball Pressure	XP Power Limited, 401 Commonwealth Drive, Haw Par Technocentre, Lobby B, #02-02, Singapore 149598
IEC 60601 1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)	11	Temperature	XP Power Limited, 401 Commonwealth Drive, Haw Par Technocentre, Lobby B, #02-02, Singapore 149598
IEC 60601 1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)	13	Abnormal Operation Testing	XP Power Limited, 401 Commonwealth Drive, Haw Par Technocentre, Lobby B, #02-02, Singapore 149598
IEC 60601 1:2005 (Third Edition) + CORR.	13.1.2	Power Availability	XP Power Limited,

1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)			401 Commonwealth Drive, Haw Par Technocentre, Lobby B, #02-02, Singapore 149598
IEC 60601 1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)	15.5.1.2	Transformer Short Circuit	XP Power Limited, 401 Commonwealth Drive, Haw Par Technocentre, Lobby B, #02-02, Singapore 149598
IEC 60601 1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)	15.5.1.3	Transformer Overload	XP Power Limited, 401 Commonwealth Drive, Haw Par Technocentre, Lobby B, #02-02, Singapore 149598

*NOTE: If testing location is blank then the test was performed at the CB Testing Laboratory as specified at the beginning of this report.*

The following datasheet enclosures are provided in this section of the report. If blank, no separate enclosures are attached.

### **Enclosures**

<u>Supplement ID</u>	<u>Description</u>
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----- END OF APPENDIX D -----