CERTIFICAT

UCB_F_12.02 2012-02



CERTIFICATE

No. B 16 07 57396 455

Holder of Certificate: XP Power LLC.

15641 Red Hill Avenue, Suite 100

Tustin CA 92780

USA

Production Facility(ies):

Product:

93389

Certification Mark:



Converter

(DC / DC Converter)

Model(s): IML02xxSyyy, IML02xxDyyy

> (where xx is 05, 12, 15 or 24 representing input voltage; yyy is 3V3 or 03, 05, 09, 12 or 15 representing output

voltage)

Parameters: Rated Input Voltage:

4.5-5.5VDC, 10.8-13.2VDC,

13.5-16.5VDC, 21.6-26.4VDC

Protection Class:

End product dependent

Elevation for Use: Temperature, Ambient: 0-5000 m above sea level 85°C max with full load

See attachment for additional information and

Conditions of Acceptability.

Tested according to: EN 60601-1:2006/A12:2014

The product was tested on a voluntary basis and complies with the essential requirements. The certification mark shown above can be affixed on the product. It is not permitted to alter the certification mark in any way. In addition the certification holder must not transfer the certificate to third parties. See also notes overleaf.

Test report no.:

095-72117476-000

Valid until:

2021-07-21

Date, 2016-07-28

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DC / DC CONVERTER

IML02xxSyyy and IML02xxDyyy, where xx 05, 12, 15 or 24 denote nominal input voltage range as:

05 = 4.5 - 5.5 Vdc

12 = 10. 8-1 3.2 Vdc

15 = 13. 5-16.5 Vdc

24 = 21.6-26.4 Vdc;

yyy = 3V3 or 03, 05, 12 or 15 representing output voltage.

Output Ratings @ 85°C:

IML02xxS3V3: 3.3Vdc, 600mA IML02xxD03: 3.3Vdc, 303mA IML02xxS05: 5 Vdc, 400mA IML02xxD05: ±5Vdc, 200mA IML02xxS09: 9Vdc, 222mA IML02xxD09: ±9 Vdc, 111mA IML02xxS12: 12Vdc, 167mA IML02xxD12: ±12Vdc, 83mA IML02xxS15: 15Vdc, 133mA IML02xxD15: ±15Vdc, 67mA

Conditions of Acceptability:

When installed in an end-product, consideration must be given to the following:

- This power supply 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.
- 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 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 enduse product shall ensure that the power supply is used within its ratings.
- The end-product evaluation shall ensure that the requirements related to Accompanying Documents, Clause 7.9 are met.

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- 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 product was tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.
- The product was not evaluated for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
- The product is a component for building in, the accessibility shall be determined as part of the end product investigation.
- 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) and Clause 17 (Electromagnetic Compatibility).
- 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.
- The product was not investigated to the following standards or clauses: Electromagnetic Compatibility (IEC 60601-1-2), Clause 14, Programmable Electronic Systems, Biocompatibility (ISO10993-1)

2016-07-28