



America

CERTIFICATE

No. B 16 01 57396 422

Holder of Certificate: XP Power LLC.



15641 Red Hill Avenue, Suite 100
Tustin CA 92780
USA

Production Facility(ies):

61661, 77041

Certification Mark:



Product:

Power supply

Model(s):

JHL03xyzz and JHL06xyzz Series
(Where xx=12 or 24 for DC input voltage, y= S or D for single or double output, zz=05, 12 or 15 for output voltage configuration.)

Parameters:

Rated Input Voltage: JHL0312yzz and JHL0612yzz: 10-17 VDC
JHL0324yzz and JHL0624yzz: 20-30 VDC
Rated Output: See attachment for output
Max temperature, ambient: 60°C

See attachment for 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.:

095-72113293-000

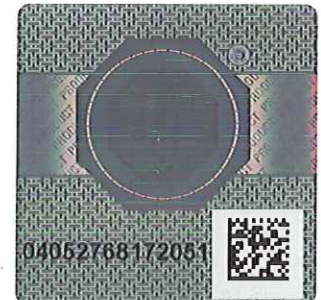
Valid until:

2021-01-24

Date, 2016-01-27

John

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ATTACHMENT TO CERTIFICATE NO. B 16 01 57396 422 FOR XP POWER LLC

POWER SUPPLY

The unit is a DC/DC Converter to be used as part of Medical Electrical Equipment, and is intended to provide Two MOPP between DC input circuits to DC output circuit.
The unit is provided with top and bottom plastic enclosure. All components inside the unit are mounted on PWB.

Approved models and Rated Outputs:

Model Number	OUTPUT RATING	
	V (VDC)	I (mA)
JHL0312S05	5	600
JHL0312S12	12	250
JHL0312S15	15	200
JHL0324S05	5	600
JHL0324S12	12	250
JHL0324S15	15	200
JHL0612S05	5	1200
JHL0612S12	12	500
JHL0612S15	15	400
JHL0624S05	5	1200
JHL0624S12	12	500
JHL0624S15	15	400
JHL0312D12	+/- 12	125
JHL0312D15	+/- 15	100
JHL0324D12	+/- 12	125
JHL0324D15	+/- 15	100
JHL0612D12	+/- 12	250
JHL0612D15	+/- 15	200
JHL0624D12	+/- 12	250
JHL0624D15	+/- 15	200

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Conditions of Acceptability:

When installing the equipment, all requirements of the standards and the manufacturer's specifications must be met.

- 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.
- The end-product evaluation shall ensure that the requirements related to Accompanying Documents, Clause 7.9 are met.
- 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.
- 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 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.
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)