



CERTIFICATE

No. B 057396 0430 Rev. 02

Holder of Certificate: XP Power LLC.

340 Commerce, Suite 100 Irvine CA 92602 USA

Certification Mark:



Product:

Power supply

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. This certificate is valid until the listed date, unless it is cancelled earlier. All applicable requirements of the Testing, Certification, Validation and Verification Regulations of TÜV SÜD Group have to be complied. For details see: www.tuvsud.com/ps-cert

Test report no.:

095-72112141104-200

Valid until:

2024-10-08

Date,

2024-03-08

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Model(s):

ECP40UD, ECP40UT Series

Brand Name:

XP

Parameters:

Rated Input Voltage: 100-240 V AC, Rated Input Current: 1-0.5 A Rated input frequency: 50/60 Hz Protection Class: Class I at end use Temperature, Ambient: 50°C with 100% rated output 70°C with 50% rated output Elevation for use 0-3000 m above sea level

The subject models are component power supplies intended for use in medical equipment. They are open frame power supplies intended for building-in the end product.

Approved models and rated output:				
Model Number	DC Output (V/A)			Maximum Power
	Output 1	Output 2	Output 3	(W)
ECP40UD01	5Vdc/5A	12Vdc/2A		40 W
ECP40UD02	5Vdc/5A	15Vdc/1.5A		40 W
ECP40UD03	5Vdc/5A	24Vdc/1A		40 W
ECP40UT01	5Vdc/5A	12Vdc/2A	-12Vdc/0.5A	40 W
ECP40UT02	5Vdc/5A	15Vdc/1.5A	-15Vdc/0.5A	40 W
ECP40UT03	5Vdc/5A	24Vdc/1A	12Vdc/0.5A	40 W
ECP40UT04	5Vdc/5A	24Vdc/1A	-12Vdc/0.5A	40 W

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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 models require:

- A suitable electrical and fire enclosure must be provided in the end use equipment.
- This power supply was evaluated with One MOPP or Two MOOP between Primary and Secondary; One MOPP or One MOOP between primary and Earth. Additional MOPP between Primary and Secondary shall be considered in the end product.
- When installed in end product, the clearance and creepage distance between the hazardous circuits and accessible parts shall meet the standard(s) requirements. Hi-pot test, touch current test and ground bond test (if applicable) shall be conducted at end product. If installed in Class I end product, unit to be properly earthed.
- 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. The output circuits have not been evaluated for direct patient connection (Type B, BF or CF).
- The end product shall ensure that the requirements related to accompanying documents, clause 7.9 are met.
- 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).
- The product was not investigated to the following standards or clauses: Biocompatibility (ISO 10993-1), Clause 14, Programmable Electronic Systems, Electromagnetic Compatibility (IEC 60601-1-2).
- Scope of Power Supply 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

Tested according to:

EN 60601-1:2006/A12:2014