ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. B 057396 0527 Rev. 00

Holder of Certificate: **XP Power LLC.**
15641 Red Hill Avenue, Suite 100
Tustin CA 92780
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. See also notes overleaf.

Test report no.: 095-72139408-000

Valid until: 2023-11-13

Date, 2018-11-22

(Ping He)

A4 / 07.17

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Product Service

CERTIFICATE

No. B 057396 0527 Rev. 00

Model(s): FCS40USxx
(where xx can be 12-48 designating the output voltage)

Brand Name: XP

Parameters:

Rated Input Voltage: 100-240 VAC
Rated Input Current: 1.2 A max
Rated Input Frequency: 50/60 Hz
Elevation for Use: 0-5000 m above sea level
Protection Class: Class I or Class II at end use
Maximum Temperature, Ambient: 50°C with 100% rated output
70°C with 50% rated output

General Product Information:
Products covered are open frame power supplies intended for building-in to be used with Medical Electrical Equipment. Units are intended for used with Class I or Class II end-products.

Approved models and Rated Outputs:

Model Number	OUTPUT RATING		
	Voltage (VDC)	Max Current (A)	Max Power (W)
FCS40US12	10.1-13.5	3.34	40
FCS40US15	13.6-17	2.67	40
FCS40US18	17.1-21	2.23	40
FCS40US24	21.1-26	1.67	40
FCS40US28	26.1-31	1.43	40
FCS40US36	33.1-42	1.11	40
FCS40US48	42.1-54	0.83	40

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Product Service

CERTIFICATE

No. B 057396 0527 Rev. 00

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

The models require:

- Suitable Mechanical, Fire and Electrical enclosure shall be provided in the end use equipment.
- Proper bonding to the end-product main protective earthing termination is required when the power supply is installed in Class I end product. Protective earthing testing shall be conducted in Class I end product application.
- Power supply provides 2 MOPP between Primary to Secondary,1 MOPP between Primary and Earth/Enclosure (Class I end product).
- 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).
- When installed in end product, the clearance and creepage distance between the related circuitry of the power supply and accessible parts shall meet the standard(s) requirements. Hi-pot test, touch current test and ground bond test (for Class I end product) shall be conducted at end product.
- Repeat of leakage current testing and consideration of non-frequency weighted leakage test shall be considered in the end product application.
- 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).

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

Production Facility(ies): 059061, 059319, 071712, 089850

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®