



Product Service

CERTIFICATE

No. B 057396 0926 Rev. 00

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 and certification regulations of TÜV SÜD Group have to be complied. For details see: www.tuvsud.com/ps-cert

Test report no.: 095-72139423-100

Valid until: 2024-10-08

Date, 2023-12-14

(Antony Young-Taylor)

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Model(s):

FCS60USxx
(where xx can be 12-48 designating the output voltage)

Brand Name: XP

Parameters:

Rated Input Voltage: 100-240 VAC
Rated Input Current: 1.6 A max
Rated Input Frequency: 50/60 Hz
Elevation for Use: 0-5000m above sea level
Protection Class: Class I or Class II at end use
Maximum Temperature, Ambient: 40°C for 60W load
50°C for 50W load
70°C for 25W load

General Product Information:

The models covered are component AC-DC power supplies intended for use in Medical Electrical Equipment. The switching power supplies are open frame type intended for building-in.

Approved models and Rated Outputs:

Model Number	OUTPUT RATING		
	Voltage (VDC)	Max Current (A)	Max Power (W)
FCS60US12	10.1-13.5	5	60
FCS60US15	13.6-17	4	60
FCS60US18	17.1-21	3.33	60
FCS60US24	21.1-26	2.5	60
FCS60US28	26.1-31	2.14	60
FCS60US36	33.1-42	1.67	60
FCS60US48	42.1-54	1.25	60

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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:

- Suitable Mechanical, Fire and Electrical enclosure shall be provided in the end use equipment.
- The end product shall ensure that the requirements related to accompanying documents, clause 7.9, are met.
- Power supply provides 2 MOPP between Primary to Secondary, 1 MOPP between Primary and Earth/Enclosure (class I end product). One MOPP between Secondary to Ground for working voltage of 48Vdc
- 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.
- 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 anaesthetic 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