



America

CERTIFICATE

No. B 11 11 57396 115

Holder of Certificate: XP Power LLC.



1241 East Dyer Road, Suite 150
Santa Ana CA 92705
USA

Production Facility(ies): 59319, 71712

Certification Mark:



Product: Power supply
(Power Supply)

Model(s): FCM400PSXX
(where XX can be number 12 to 48 to indicate the main output voltage, may be also followed by suffix "SF" for single fuse option)

Parameters:

Rated Input Voltage:	100-240 V AC,
Rated Input Current:	5 A
Rated input Frequency:	50/60 Hz
Rated Output Ratings:	See attachment for output ratings and conditions of acceptability.
Protection Class:	I at end use
Temperature, Ambient:	50°C with maximum output power, 70°C with half maximum output power

See attachment for further information

Tested according to: EN 60601-1:2006

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.: 095-1110075-000

Date, 2011-11-08

Page 1 of 3

More





America

**ATTACHMENT TO CERTIFICATE NO. B 11 11 57396 115
FOR XP POWER LLC**

POWER SUPPLY

Approved models and output ratings:

Model Number	OUTPUT RATING			
	Main output voltage (VDC)	Main output current (A)	Standby voltage (VDC)	Standby current (A)
FCM400PS12	12	33.3	5	0.5
FCM400PS15	15	26.6	5	0.5
FCM400PS24	24	16.6	5	0.5
FCM400PS28	28	14.2	5	0.5
FCM400PS36	36	11.1	5	0.5
FCM400PS48	48	8.3	5	0.5

Conditions of Acceptability:

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

The models require:

- The products were tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.
- Suitable Fire/Mechanical/Electrical enclosure shall be provided as part of the end product.
- When installed into end product, sufficient clearance and creepage distance shall be provided between power supply and protectively earthed accessible conductive parts .
- 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 circuits have not been evaluated for direct patient connection (Type B, BF or CF).
- The input/output connectors are not acceptable for field connections, they are only intended for factory wiring inside the end-use product.
- The power supplies have not been evaluated for use in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.
- Proper bonding to the end-product main protective earthing terminal is required when the power supply is installed in the end product,
- The power supply may be provided with one fuse in the Line side or fuses in both the Line and Neutral sides. The need of additional fusing shall be determined as part of end-production evaluation.

(continued)



America

ATTACHMENT TO CERTIFICATE NO. B 11 11 57396 115 FOR XP POWER LLC

- Scope of Power Supply evaluation defers the following clauses to 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 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

None



America

CERTIFICATE

No. B 10 09 57396 081

Holder of Certificate: XP Power LLC.



1241 East Dyer Road, Suite 150
Santa Ana CA 92705
USA

Production Facility(ies):

59319, 71712

Certification Mark:



Product:

**Power supplies
(Power Supply)**

Model(s):

FCM400PSXX
(where XX can be number 12 to 48 to indicate the main output voltage, can be provided with additional suffix "SF" for single pole fusing and/or "S" for screw input terminal)

Parameters:

Rated Input Voltage:	100-240 V AC
Rated Input Current:	5 A
Rated input frequency:	50/60 Hz
Protection Class:	I at end use.
Temperature, Ambient:	50°C with maximum output power, 70°C with half maximum output power.
Elevation for use:	0-3000 m above sea level.
Rated Output Ratings:	See attachment for output ratings and conditions of acceptability.

Tested according to: EN 60950-1/A11:2009

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.: 095-1008816-000

Date, 2010-10-04

Page 1 of 2





America

**ATTACHMENT TO CERTIFICATE NO. B 10 09 57396 081
FOR XP POWER LLC**

POWER SUPPLY

Approved models and output ratings:

Model Number	MAIN OUTPUT RATING			Standby Output Rating	
	Voltage (VDC)	Maximum Current (A)	Maximum Output Power (W)	Voltage (VDC)	Current (A)
FCM400PS12	12	33.3	400	5	0.5
FCM400PS15	15	26.6	400	5	0.5
FCM400PS24	24	16.6	400	5	0.5
FCM400PS28	28	14.2	400	5	0.5
FCM400PS36	36	11.1	400	5	0.5
FCM400PS48	48	8.3	400	5	0.5

Model Differences:

All models are similar with the differences in Main Transformer T3, and minor secondary components for different output voltages.

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.
- Proper bonding to the end-product main protective earthing terminal is required when the power supply is installed in the end product.
- The following input terminals/connectors must be connected to the end product neutral: CON2.
- Ground bond test, Touch current test and dielectric Strength test need to be considered at end use equipment.
- The proper warning to service persons should be marked on the end product when the power supply has a fuse in the neutral of the primary circuit.
- The output has energy higher than 240 VA, additional compliance at end use.

Report Reference Number: 095-1008816-000

2010-10-04

Page 2 of 2