America

CERTIFICATE

No. B 18 04 57396 493

Holder of Certificate: **XP Power LLC.**
15641 Red Hill Avenue, Suite 100
Tustin CA 92780
USA

Production Facility(ies): 59061, 59319, 71712, 89850

Certification Mark:

tuv-sud.com/ps-cert

Product: **Power supply**

Model(s): **SMP350PSxx**
(where xx can be any number between 12 and 48 may also be provided with additional suffix "SF" for single pole fusing)

Parameters:

Rated Input Voltage:	100-240 VAC
Rated Input Current:	4.9 A
Elevation for use:	0-5000 m above sea level
Protection Class:	Class I at end use
Max temperature, ambient:	50°C with 100% output power 70°C with 50% output power

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.: 095-72137679-000

Valid until: 2023-04-03

Date, 2018-04-10

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ATTACHMENT TO CERTIFICATE NO. B 18 04 57396 493 FOR XP POWER LLC

POWER SUPPLY

General Product information:

The models covered are Class I build-in component power supply intended for use in Class I Medical Equipment.

Approved models and Rated Outputs:

Model Number	OUTPUT RATING		
	Voltage (VDC)	Max Current (A)	Max Power (W)
SMF350PS12	10.1-13.5	25	300
SMF350PS15	13.6-17	22	330
SMF350PS18	17.1-21	19.4	350
SMF350PS24	21.1-26	14.6	350
SMF350PS28	26.1-31	12.5	350
SMF350PS33	31.1-33	10.6	350
SMF350PS36	33.1-42	9.70	350
SMF350PS48	42.1-54	7.30	350

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 the end product.
- Power supply provides the following MOPP (means of patient protection): 2 MOPP based upon a working voltage 240 Vrms, 340 Vpk between Primary to Secondary,1 MOPP based upon a working voltage 240 Vrms, 340 Vpk between Primary and Earth/Enclosure, and 1 MOPP based upon a working voltage 48 Vrms between Secondary and Earth/Enclosure.
- Repeat of leakage current testing and consideration of non-frequency weighted leakage test shall be considered in the end product application.
- Consideration should be given to measuring the temperature on power electronic components and transformer windings when the power supply is installed in the end-use equipment. The end-use product shall ensure that the power supply is used within its ratings
- 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).
- Protective earthing testing shall be conducted in the end product application.
- The following clauses are to the be determined as part of the end product evaluation: Clause 7.5 (Safety Signs), Clause 7.9 (Accompanying Documents), Clause 8 (Electrical Hazard) Clause 9 (ME Hazard), Clause 10 (Radiation), Clause 11 (Temperature), Clause 12 (Controls), Clause 13 (SFC/Abnormals), Clause 14 (PEMS), Clause 15, 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).