



America

CERTIFICATE

No. B 15 06 57396 334

Holder of Certificate: **XP Power LLC.**



15641 Red Hill Avenue, Suite 100
Tustin CA 92780
USA

Production Facility(ies): 71712, 59319, 89850

Certification Mark:



Product: **Power supply
(Power Supply)**

Model(s): **EMH250PS Series , EMH350PS Series
(see approved models section for model details)**

Parameters:

Rated Input Voltage:	100-240 V AC,
Rated Input Current:	3.8 A (EMH250PS Series), 4.8 A (EMH350PS Series)
Rated Input Frequency:	50/60 Hz
Rated Output Ratings:	See attachment
Protection Class:	I or II end use
Temperature, Max Ambient:	With 12 CFM force air cooling: 50°C with maximum output power, 70°C with half maximum output power
Elevation for use:	0-3000 m above sea level.
See attachment for further information	

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.

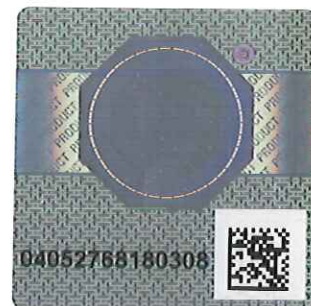
Test report no.: 095-72106032-000

Valid until: 2020-06-04

Date, 2015-06-08

Page 1 of 3

None





America

ATTACHMENT TO CERTIFICATE NO. B 15 06 57396 334 FOR XP POWER LLC

POWER SUPPLY

Models covered in this report are component type AC to DC power supplies intended for use in Medical equipment. They are power supplies for building-in Class I or Class II end product.

Approved Models and output ratings:

Model Number	MAIN OUTPUT RATING		
	Voltage (VDC)	Max Current (A)	Max output power (W)
EMH250PS12	10.1-13.5	21	250
EMH250PS15	13.6-17	16.7	250
EMH250PS18	17.1-21	14	250
EMH250PS24	21.1-26	10.5	250
EMH250PS28	26.1-31	9.0	250
EMH250PS33	31.1-33	7.6	250
EMH250PS36	33.1-42	6.9	250
EMH250PS48	42.1-54	5.2	250
EMH350PS12	10.1-13.5	29.2	350
EMH350PS15	13.6-17	23.3	350
EMH350PS18	17.1-21	19.5	350
EMH350PS24	21.1-26	14.6	350
EMH350PS28	26.1-31	12.5	350
EMH350PS33	31.1-33	10.6	350
EMH350PS36	33.1-42	9.8	350
EMH350PS48	42.1-54	7.3	350
EMH350PS12-01 XB0188	10.1-13.5	29.2	350
EMH350PS12-XA1007	12.3	28.5	350
Stand-by dc output: for all models except EMH350PS12-01 XB0188 and EMH350PS12-XA1007: 5Vdc/2A; EMH350PS12-01 XB0188: 12V/0.8A; EMH350PS12-XA1007: 5.1 V/ 10W. Fan output for all models: 12Vdc/0.6A (optionally marked on nameplate).			

Model number can be optionally followed by:

-yy, yy= 00-99, denotes non-safety related functions; then optionally followed by "SF" or "-SF", denotes single pole fusing (blank: double fusing);

Model number can optionally provided with suffix:

"-TF", "-VF" : top fan and cover;

"-S": models provided with input screw terminals;

"D": models provided with integral O-ring diode located in the secondary.



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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:

- Power supply provides the following MOPP (means of patient protection): two MOPP between Primary to Secondary, one MOPP between Primary and Earth/Enclosure, two MOPP between secondary to floated earth trace on PWB as Class II application for BF output consideration, one MOPP between secondary and earthing trace or chassis as Class I application for BF output consideration.
- 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 connection to mating connectors of the end use equipment. .
- Proper bonding to the end-product main protective earthing terminal is required when the power supply is installed in Class I end product.
- Primary Heatsink was considered floating live and should not be connected to earth in the end-product.
- The "floating" mounting hole shall be mounted on insulating post or properly earthed for Class I end product.
- Units provided with either a Cover or Chassis should be used only in a Class I application with earthing symbol applied. The cover and chassis shall be reliably earthed in the end-use application.
- When installed in a Class I end product, and if the Chassis and Cover are not provided, the power supply shall be mounted in a manner that provides sufficient Clearance and creepage between the primary side of the power supply and protectively earthed accessible conductive parts. In addition, when installed in a Class I end product, the protective bonding terminal of the power supply shall be reliably connected to the main protective earthing terminal of the end product.
- When installed in a Class II end product, the power supply shall be mounted, on insulating posts, in a manner that provides sufficient Clearance and creepage between the primary side of the power supply and any accessible conductive parts.
- Units may be provided with one fuse in the Line side for models with SF suffix or one fuse in both the Line and Neutral sides. The need for additional fusing shall be determined as part of the end-product evaluation.
- 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).