



America

CERTIFICATE

No. B 14 10 57396 286

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

Model(s): GSP500PSxxy
(where xx can be number between 12 to 48 for output voltage; y can be "P" or blank, may be followed by followed by "-EF" or/and "-SF". All "-" are optional)

Parameters:

Rated Input Voltage:	100-240 VAC
Rated Input Current:	6.5 A
Rated input frequency:	50/60 Hz
Elevation for use:	0-5000 m above sea level
Protection Class:	Class I
Maximum temperature, ambient:	50°C with max output power, 70°C with 50% max output power
Others:	See attachment for output ratings and Conditions of Acceptability.

Tested according to: EN 60601-1/A1:2013

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.

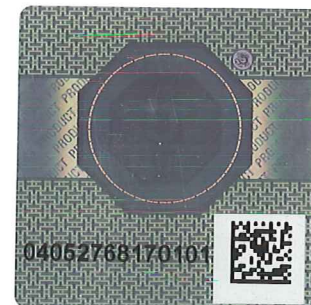
Test report no.: SI1409601-000

Valid until: 2019-10-24

Date, 2014-11-19

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POWER SUPPLY

General Product information:

Models below are component power supplies intended for use in medical equipment. They are open frame power supplies intended for building-in Class I end product.

Approved models and Rated Outputs:

Model Number	OUTPUT (Convection Cooling)			OUTPUT (Forced Cooling)		
	Voltage (VDC)	Current (A)	Max. Power (W)	Voltage (VDC)	Current (A)	Max. Power (W)
GSP500PS12	10.1-13.5	17	180	10.1-13.5	42	500
GSP500PS15	13.6-17	12	180	13.6-17	33.33	500
GSP500PS18	17.1-21	10	180	17.1-21	27.7	500
GSP500PS24	21.1-26	7.5	180	21.1-26	21	500
GSP500PS28	26.1-31	6.43	180	26.1-31	17.86	500
GSP500PS36	33.1-42	5	180	33.1-42	13.89	500
GSP500PS48	42.1-52	3.75	180	42.1-52	10.5	500

Stand-by output for all models: 5Vdc/2A
Fan output for all models" 12 Vdc/0.3A

Suffix:
EF: Provided with build in end fans,
SF: Provided with single pole fusing,
P: Construction variation to current sensing transformer T100.

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 based upon a working voltage 284 Vrms, 475 Vpk between Primary to Secondary, one MOPP based upon a working voltage 241 Vrms, 343 Vpk between Primary and Earth/Enclosure, one MOPP based upon on working voltage 48Vdc or Functional between secondary output to ground
- The power supply terminals and/or connectors are: Not investigated for field wiring
- Proper bonding to the end-product main protective earthing termination is: Required.
- The following input terminals/connectors must be connected to the end-product supply neutral: Input Connector (CON1) N terminal.
- The following end-product enclosures are required: Electrical, Mechanical, Fire.
- Suitable disconnect device is to be provided in the end system.

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- Temperature, Leakage and Dielectric Strength testing shall be considered in the end system and consideration of non-frequency weighted leakage current (clause 8.7.3e) to also be considered as part of the end product.
- Units provided with additional suffix "SF", provided with only one fuse. The need for additional fusing shall be determined as part of the end product.
- Heatsinks are floating and considered live. They should not be accessible in the end-product.
- The device shall be installed in compliance with the enclosure, mounting, spacing, casualty, markings, and segregation requirements of the end-use application.
- ME Equipment is component for building-in. Applicability of the following is to be determined in End Product Evaluation: 5.9 - Accessibility, 7 - Identification marking and Documents, 8.4.2 – Accessible Parts Including Applied Parts, 8.6 - Protective Earthing, 8.11.1 - Isolation from Supply Mains, 8.11.3 - Power Supply Cords, 9 - Protection against mechanical hazards, 11.3 - Fire Enclosure, 11.8 - Interruption of power supply, 15.3 - Mechanical Strength, 15.4.1 - Construction of Connectors, 15.4.4 – Indicators.
- Overcurrent releases of adequate breaking capacity must be employed in the end product.
- The component shall be considered for compliance with the Marking (clause 7) and Separation (clause 8) requirements as part of the end use application evaluation.
- The available voltage for the secondary outputs does not exceed 25 Vac or 60 Vdc, under normal and single fault conditions. The power supply shall be mounted in manner that it provides sufficient clearance and creepage distances between the hazardous parts and protectively earthed accessible conductive parts.
- Cleaning test shall be considered as part of end product evaluation.
- The need for Marking Durability and Marking Legibility Testing shall be considered as part of the end product installation.
- Fire/ Mechanical/ Electrical Enclosure to be provided as part of the end product.
- Models covered under this Report have been evaluated for 50°C and 70°C ambient with either an end fan option or 15 cfm external air-flow for open frame and U-channel options applied at chassis edge (near C20 and D60).
- The product was not investigated to the following standards or clauses: Electromagnetic Compatibility (IEC 60601-1-2), Clause 14, Programmable Electronic Systems, Biocompatibility (ISO 10993-1)

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