

CERTIFICATE

No. B 16 11 57396 463

Holder of Certificate: XP Power LLC.

15641 Red Hill Avenue, Suite 100 Tustin CA 92780

USA

Production Facility(ies):

59319, 71712, 89850, 59061

Certification Mark:





Product:

Power supply

Model(s):

GCS350PSxx, AVPQ150M165170z

(where xx can be any number between 12 and 56 for output voltage; may be optionally followed by "-C" or "-TF" or "-EF" or blank, may also be provided with additional suffix "SF", "S", or "J". All "-" are optional. "z" is optional and may be represented by any letter A-Z corresponding to

non-safety related options.)

Parameters:

Rated Input Voltage:

100-240 V AC 50/60 Hz

Rated Frequency: Rated Input Current:

4.9 A (GCS350PSxx),

tod outputs

1.9 A (AVPQ150M165170z)

Rated output: Protection Class: See attachment for output information

Class I or Class II at end use

See attachment for additional detail and conditions of

acceptability

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.:

095-72105904-100

Valid until:

2021-11-27

Date, 2016-11-30

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POWER SUPPLY

Approved models and Rated Outputs:

M. J. M	DC OUTPUT (with 7 CFM Forced Cooling)					
Model Number	V1 Voltage (V)	Max. Current (A)	Total Power (W)			
GCS350PS12	10.1-13.5	29.2	350			
GCS350PS15	13.6-17	23.3	350			
GCS350PS18	17.1-21	19.4	350			
GCS350PS24	21.1-26	14.6	350			
GCS350PS28	26.1-31	12.5	350			
GCS350PS33	31.1-33	10.6	350			
GCS350PS36	33.1-42	9.72	350			
GCS350PS48	42.1-54	7.29	350			
GCS350PS56	54.1-60	6.25	350			

Suffix:

C: Provided with cover,

TF: Provided with top fan,

EF: Provided with end fan,

SF: Provided with single pole fusing,

S: Provided with screw terminal block,

J: Provided with suffix "J" employs dual row output connector (J2),

Models without suffix "C", "TF" or "EF" are open frame models (without cover).

AVPQ150M165170z:

Output 1: 16.3 Vdc, 6 A; Output 2: 5.1 Vdc, 10 A. (149 W max); when operated at 55°C. Output 1: 16.3 Vdc, 3 A; Output 2: 5.1 Vdc, 5 A. (75 W max); when operated at 70°C.

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GCS350 Series Output Ratings:

Model M	Convectional Cooling								
	Max Output @50°C	Max Output @70°C	w/ Cover Max Output @50°C	w/ Cover Max Output @70°C	Max Output @40°C	w/ Cover Max Output @40°C	Max Output @30°C	w/ Cover Max Output @30°C	
GC\$350P\$12	175W; 14.6A	87.5W; 7.3A	130W; 10.8A	65W; 5.42A	200W; 16.67A	170W; 14.17A	225W; 18.75W	175W; 14.6A	
GC5350PS15	175W; 11.7A	87.5W; 5.83A	130W; 8.67A	65W; 4.33A	200W; 13.33A	170W; 11.33A	225W; 15A	175W; 11.7A	
GC5350PS18	175W; 9.72A	87.5W; 4.86A	130W; 7.22A	65W; 3.61A	200W; 11.11A	170W; 9.44A	225W; 12.5A	175W; 9.72A	
GC5350P524	175W; 7.3A	87.5W; 3.65A	130W; 5.42A	65W; 2.71A	200W; 8.3A	170W; 7.1A	225W; 9.38A	175W; 7.3A	
GC\$350P\$28	175W; 6.25A	87.5W; 3.13A	130W; 4.64A	65W; 2.32A	200W; 7.14A	170W; 6.07A	225W; 8.04A	175W; 6.25A	
GC\$350P\$33	175W; 5.30A	87.5W; 2.65A	130W; 3.94A	65W; 1.97A	200W; 6.06A	170W; 5.15A	225W; 6.82A	175W; 5.30A	
GC5350P536	175W; 4.86A	87.5W; 2.43A	130W; 3.61A	65W; 1.81A	200W; 5.56A	170W; 4.72A	225W; 6.25A	175W; 4.86A	
GC5350PS48	175W; 3.65A	87.5W; 1.82A	130W; 2.71A	65W; 1.35A	200W; 4.17A	170W; 3.54A	225W; 4.69A	175W; 3.65A	
GC\$350P\$56	175W; 3.12A	87.5W; 1.56 A	130W; 2.32A	65W; 1.16A	200W; 3.57A	170W; 3.04A	225W; 4.02A	175W; 3.13A	

	Force	Top Fan/End Fan			
w/Cover Max Output @50°C (15 cfm)	w/Cover Max Output @70°C (15 cfm)	Max Output @50°C (15 cfm)	Max Output @70°C (15 cfm)	Max Output @50°C	Max Output @70°C
350W; 29.2A	175W; 14.6A	350W; 29.2A	175W; 14.6A	350W; 29.2A	175W; 14.6A
350W; 23.3A	175W; 11.7A	350W; 23.3A	175W; 11.7A	350W; 23.3A	175W; 11.7A
350W; 19.4A	175W; 9.72A	350W; 19.4A	175W; 9.72A	350W; 19.4A	175W; 9.72A
350W; 14.6A	175W; 7.3A	350W; 14.6A	175W; 7.3A	350W; 14.6A	175W; 7.3A
350W; 12.5A	175W; 6.25A	350W; 12.5A	175W; 6.25A	350W; 12.5A	175W; 6.25A
350W; 10.6A	175W; 5.30A	350W; 10.6A	175W; 5.30A	350W; 10.6A	175W; 5.30A
350W; 9.72A	175W; 4.86A	350W; 9.72A	175W; 4.86A	350W; 9.72A	175W; 4.86A
350W; 7.29A	175W; 3.65A	350W; 7.29A	175W; 3.65A	350W; 7.29A	175W; 3.65A
350W; 6.25A	175W; 3.12A	350W; 6.25A	175W; 3.12A	350W; 6.25A	175W; 3.12A

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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:

- The power supply was evaluated for use in ambient ranging from 30° C to 70° C depending upon the configuration. See the Output Ratings Table.
- The following end-product enclosures are required: Mechanical, Fire, Electrical.
- For an open frame (forced air) configuration without the Top or End Fan, the maximum continuous power supply output (Watts) relied on forced air cooling from: 15 cfm fan applied 1 inch from input side, blowing inward.
- This power supply was evaluated with Two MOPP between Primary and Secondary for 304Vpk/240Vrms; One MOPP primary and Earth for 340Vpk/240Vrms; Two MOPP between Secondary to Ground for working voltage of 60Vdc and 1 MOPP for working voltage of 240Vrms between Secondary and Earth of BF output considerations.
- Repeat of leakage current testing and consideration of non-frequency weighted leakage test shall be considered in the 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 anesthetic mixture with air, oxygen, or nitrous oxide. The output circuits have not been evaluated for direct patient connection (Type B, BF or CF).
- Models provided with suffix SF only provided with one line side fuse. Consideration should be made in the end-use product to determine the need of double pole fusing.
- When installed in a Class II end product, the power supply shall be mounted in a manner that provides sufficient clearance and creepage distance between the hazardous parts and accessible conductive parts.
- Proper bonding to the Class I end-product main protective earthing termination is required (via mounting holes on the PCB), unless for Class II applications. For Class II applications the primary side mounting pads are isolated from accessible conductive chassis by Reinforced Insulation.
- Protective earthing testing shall be conducted in the end product application.
- Model AVPQ150M165170 secondary output of power supply GCS350PS15 is connected to ground.
- Scope of Power Supply evaluation defers the following clauses to the 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.
- 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).

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