



America

# CERTIFICATE

No. B 16 04 57396 424

**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

**Model(s):**

GCS265PSxx, GCS265PS36-XB0599  
(where xx can be number between 12 to 56 for output voltage;  
may be optionally followed by "-C" or "-TF" or "-EF" or  
blank, may also be provided with additional suffix "SF"  
or "S" or "R". All "." are optional)

**Parameters:**

Rated Input Voltage:	100-240 V AC
Rated Frequency:	50/60 Hz
Rated Input Current:	3 A
Rated output:	See attachment for output information
Protection Class:	Class I or Class II at end use
Temperature, Ambient:	50°C with 100% rated output with forced cooling 70°C with 50% rated output with forced cooling
Others:	See attachment for 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.

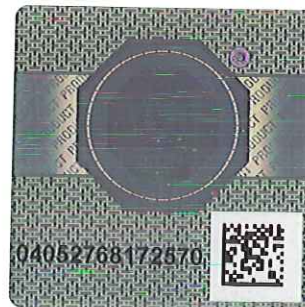
**Test report no.:** 095-72115789-000

**Valid until:** 2021-04-12

**Date,** 2016-04-19

*John*

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# ATTACHMENT TO CERTIFICATE NO. B 16 04 57396 424 FOR XP POWER LLC.

## POWER SUPPLY

### General Product information:

Models covered in this report are component power supplies intended for use in medical equipment. They are open frame power supplies intended for building-in Class I or Class II end product.

### Approved models and Rated Outputs:

Model Number	DC OUTPUT (with 7 CFM Forced Cooling)		
	V1 Voltage (V)	Max. Current (A)	Total Power (W)
GCS265PS12	10.1-13.5	20.8	250
GCS265PS15	13.6-17	16.7	250
GCS265PS18	17.1-21	13.9	250
GCS265PS24	21.1-26	10.4	250
GCS265PS28	26.1-31	8.9	250
GCS265PS33	31.1-33	7.6	250
GCS265PS36	33.1-42	6.9	250
GCS265PS48	42.1-54	5.2	250
GCS265PS56	54.1-60	4.5	250
GCS265PS36-XB0599	36	6.95	250

All models have a standby output: 5 Vdc/3A.

### 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,
  - R: Provided with Remote inhibit
- Models without suffix "C", "TF" or "EF" are open frame models (without cover).



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## ATTACHMENT TO CERTIFICATE NO. B 16 04 57396 424 FOR XP POWER LLC.

### Conditions of Acceptability:

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

#### The models require:

- The following end-product enclosures are required: Mechanical, Fire, Electrical.
- The input/output connectors are not acceptable for field connections; they are only intended for connection to mating connectors of the end-use equipment.
- Power supply provides the following MOPP (means of patient protection): 2 MOPP based upon a working voltage 336 Vpk, 240 Vrms between Primary to Secondary, one MOPP based upon a working voltage 352Vpk, 244 Vrms between Primary and Earth/Enclosure, and 1 MOPP based upon a working voltage 250Vac between secondary to earth trace on PWB.
- 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 maximum continuous power supply output (Watts) relied on forced air cooling from: 7 cfm fan applied 1 inch from input side, blowing inward.
- Fans: For models with the suffix "EF", the fan provided in this sub-assembly is not intended for operator access, For models with the suffix "TF", the fan provided in this sub-assembly is provided with a fan guard to reduce the risk of operator contact with the stator.
- 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. For Class II applications the primary side mounting pads are isolated from accessible conductive chassis by Reinforced Insulation.
- 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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Date: 2016-04-19