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America

CERTIFICATE

No. B 15 06 57396 331

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

15641 Red Hill Avenue, Suite 100
Tustin CA 92780
USA

Production Facility(ies): 59319, 71712, 89850

Certification Mark:

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

Model(s): **CHD250xxyy**
(where "xx" can be any number between 12 to 48 indicating main output voltage, "yy" can be SF indicating Single Fuse or blank, may also be provided with additional suffixes "-S", "-C", "-L", and/or "A").

Parameters:

Rated Input Voltage:	100-240 VAC
Rated Frequency:	50/60 Hz
Rated Input Current:	3.1 A max
Rated Output Ratings:	See attachment for output ratings
Protection Class:	Class I at end use
Elevation for use:	0-5000 m above sea level
Tamb:	50°C at maximum output ratings 70°C at lower output ratings, see attachment

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.: 095-72105960-000

Valid until: 2020-06-02

Date, 2015-06-08

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ATTACHMENT TO CERTIFICATE NO. B 15 06 57396 331 FOR XP POWER LLC

SWITCHING POWER SUPPLY

Approved models and Rated Outputs:

Model Number	OUTPUT RATING		
	Voltage (VDC)	Max Current (A)	Max Output power (W)
CHD250PS12	10.1 to 13.5	20.8	250
CHD250PS15	13.6 to 17	16.7	250
CHD250PS18	17.1 to 21	13.9	250
CHD250PS24	21.1 to 26	10.4	250
CHD250PS28	26.1 to 31	8.93	250
CHD250PS33	31.1 to 33	7.58	250
CHD250PS36	33.1 to 42	6.94	250
CHD250PS48	42.1 to 54	5.2	250

Model	Convectional Cooling		Convectional Cooling With 5V Standby		Convectional Cooling With Cover		Convectional Cooling With Cover and and 5V Standby	
	Max Output @50°C	Max Output @70°C	Max Output @50°C	Max Output @70°C	Max Output @50°C	Max Output @70°C	Max Output @50°C	Max Output @70°C
CHD250PS12	250W; 20.8A	200W; 16.67A	255W; 20.8A, 1A	127.3W; 10.4A, 0.5A	217W; 18.1A	108.5W; 9.04A	165W; 13.33A, 1A	82.5W; 6.67A, 0.5A
CHD250PS15	250W; 16.7A	200W; 13.33A	255W; 16.7; 1A	127.3W; 8.33A; 0.5A	217W; 14.5A	108.5W; 7.23A	165W; 10.7A; 1A	82.5W; 5.33A, 0.5A
CHD250PS18	250W; 13.9A	200W; 11.11A	255W; 13.9A; 1A	127.3W; 6.94A, 0.5A	217W; 12.1A	108.5W; 6.03A	165W; 8.89A; 1A	82.5W; 4.44A; 0.5A
CHD250PS24	250W; 10.4A	200W; 8.33A	255W; 10.4A, 1A	127.3W; 5.2A, 0.5A	217W; 9.04A	108.5W; 4.52A	165W; 6.67A, 1A	82.5W; 3.33A, 0.5A
CHD250PS28	250W; 8.93 A	200W; 7.14A	255W; 8.93A; 1A	127.3W; 4.46A, 0.5A	217W; 7.75A	108.5W; 3.88A	165W; 5.71A; 1A	82.5W; 2.86A; 0.5A
CHD250PS33	250W; 7.58A	200W; 6.1A	255W; 7.58A; 1A	127.3W; 3.79A, 0.5A	217W; 6.58A	108.5W; 3.29A	165W; 4.84A, 1A	82.5W; 2.42A, 0.5A
CHD250PS36	250W; 6.94A	200W; 5.56A	255W; 6.94A, 1A	127.3W; 3.47A; 0.5A	217W; 6.03A	108.5W; 3.01A	165W; 4.44A, 1A	82.5W; 2.22A, 0.5A
CHD250PS48	250W; 5.2A	200W; 4.17A	255W; 5.2A, 1A	127.3W; 2.6A; 0.5A	217W; 4.52A	108.5W; 2.26A	165W; 3.33A, 1A	82.5W; 1.67A, 0.5A

Suffix:

SF: single fuse provided in the line side of the primary.
-C: unit provided with cover;
-S: unit provided with screw terminal;
-L: unit provided with input leads;
-A: unit provided with 5V Stand-by output rated 5Vdc, 1A.

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Conditions of Acceptability:

The models require:

- The following end-product enclosures are required: Mechanical, Fire, Electrical.
- The power supplies were evaluated as having 2 MOPP between primary-to-secondary for 292Vrms, 478Vpk, and 1 MOPP between primary-to-ground for 240Vac and 420Vpk. Models CHD250PSxxyy where xx is 12 to 36 only were also evaluated for 2 MOPP between secondary to ground for working voltage of 42Vdc and 1 MOPP for a working voltage of 250Vrms between secondary and earth for BF output considerations.
- 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
- Temperature, Leakage and Dielectric Strength testing shall be considered in the end system.
- 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.
- Protective earthing testing shall be conducted in the end product application.
- Heatsinks are floating and considered live. They should not be accessible in the end-product.
- 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).