

CERTIFICATE

No. B 12 01 57396 133

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:

Switching power supply unit (Switching Power Supply)

Model(s):

CLC175USXX-M

(where XX can be number 12 to 48 to indicate the main output voltage, may be also followed by suffix "-SF","A", "C" or "TF" for different

configurations)

Parameters:

Rated Input Voltage:

100-240 V AC,

Rated Frequency: Rated Input Current: 50/60 Hz 3.1 A

Rated Output Ratings: Protection Class:

See attachment Class I or Class II

depends on end use

Temperature, Ambient:

50°C for maximum output power,

70°C for half maximum output power.

12CFM fan cooling.

See attachment for further information.

Tested according to: EN 60601-1:2006

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.:

095-1200523-000

Date, 2012-01-23

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SWITCHING POWER SUPPLY

CLC175USXX-M Rated Outputs:

OLO 17000XX-III Nated Outputs.				
Model Number	OUTPUT RATING		OUTPUT RATING	
	50°C ambient		70°C ambient	
	Voltage	Current (A)	Voltage	Current (A)
	(VDC)		(VDC)	
CLC175US12-M	12	13.9	12	7
CLC175US24-M	24	6.9	24	3.45
CLC175US48-M	48	3.5	48	1.75
All models are provided with Fan output (12Vdc, 0.5A) and Standby output (5.0Vdc, 0.5A).				

Model Differences:

All models are similar with the differences in the Mains Transformer T1 and minor secondary components that allow for different main output voltage.

Suffix

"SF": single fuse provided in the line side of the primary.

"TF": units provided with cover and top fan.

"C": units provided with cover.

"A" units provided with Transformer T2.

Conditions of Acceptability:

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

The models require:

- Suitable Fire/Mechanical/Electrical enclosure shall be provided as part of the end product.
- When installed into end product, sufficient clearance and creepage distance shall be provided between power supply and accessible conductive parts.
- 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.
- The power supplies have not been evaluated for use in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.
- Proper bonding to the end-product main protective earthing terminal is required when the power supply is installed in the Class I end product.
- Units may be optionally provided with one fuse in the Line side for models with SF suffix. The need for additional fusing shall be determined as part of the end-product evaluation.

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- Temperature test conducted with approx 12CFM top fan model forced air cooling, temperature on Convection cooling condition or other external forced air cooling shall be determined in the end system.
- The product was not investigated to the following standards or clauses: Electromagnetic Compatibility (EN 60601-1-2) Clause 14, Programmable Electronic Systems, Biocompatibility (ISO 10993-1), additional evaluation shall be conducted at end use.
- 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

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

Flammable Anesthetic Mixtures Protection: Annex G

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