

CERTIFICATE

No. B 14 05 57396 263

Holder of Certificate:

XP Power LLC.

XP

1241 East Dyer Road, Suite 150 Santa Ana CA 92705

USA

Production Facility(ies):

61661, 77041

Certification Mark:



Product:

Power supply (Power Supply)

Model(s):

EML15USxx-y (xx= 03, 05, 09, 2, 15, 24, 36

or 48; y= P, T, E, S or SD)

Parameters:

Rated Input Voltage:

100-240 V AC,

Rated Input Current:

0.4-0.2 A

Rated input frequency:

50/60 Hz See attachment

Rated Output Ratings: Protection Class:

Class II

Temperature, Ambient:

50°C with maximum output power

70°C with half maximum output power.

See attachment for additional 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.:

SI1404776-000

Date, 2014-05-15

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ATTACHMENT TO CERTIFICATE NO. B 14 05 57396 263 FOR XP POWER LLC

POWER SUPPLY

Product Description

The subject product is a component power supply intended to be used as part of Medical Electrical Equipment.

Unit is assessed as Class II power supply providing 2MOPP between input and output (all versions), and between input and outer surface of plastic enclosure (encapsulated version).

The power supply is maintenance free.

Model Differences

Models are electrically similar with exception to the Mains Transformer (T1) - secondary windings, and minor secondary components that allow for different output voltage ratings. See Enclosure "Miscellaneous" 7-01 for details.

Suffixes P, T, E, S and SD define the following construction differences:

- P PCB mount;
- T chassiss mount;
- E encapsulated;
- S provided with screw terminals;
- SD screw terminals with DIN clip attached.

Model Number	Output Voltage (Vdc)	Nominal Output Cutrrent (A)	Output Power (W)
EML15US03	3.3	3.00	10
EML15US05	5.0	3.00	15
EML15US09	9.0	1.67	15
EML15US12	12.0	1.25	15
EML15US15	15.0	1.00	15
EML15US24	24.0	0.63	15
EML15US36	36.0	0.42	15
EML15US48	48.0	0.32	15

Remarks:

- The output circuits have not been evaluated for direct patient connection (Type B, BF or CF).
- The power supply was not evaluated for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

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Engineering Conditions of Acceptability

When installed in an end-product, consideration must be given to the following:

- Consideration should be given to measuring the temperature on power electronic components and transformer windings when the power supply is installed in the end-use equipment. The end use product shall ensure that the power supply is used within its ratings. --
- Leakage Current Testing, including when measured with a non-frequency-weighted device (Clause 8.7.3e), shall be considered in the end product application. --
- The power supply provides 2MOPP between input and output (all versions), and between input and plastic enclosure (encapsulated version)., --
- The products were tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary. --
- The end product should ensure that the requirements related to accompanying documents, clause 7.9. are met --
- The need for Marking Durability and Marking Legibility Testing to be considered as part of the end product installation --
- Fire/ Mechanical/ Electrical Enclosure to be provided as part of the end product --
- The end-product Electric Strength Test is to be based upon a maximum working voltage of Primary-SELV: 492 Vpk. --
- Power supply employs mains fuses with less than 1500A @ 250 V breaking capacity. The issue needs to be addressed in end-product RM file, and necessary evaluation conducted during end-use product certification --
- Power supply has no mains disconnect device; suitable device(s) shall be provided in end-use product. --
- Component is not provided with symbol 9 of Table D.1 (symbol IEC 60417-5172, DB: 2003-02). Enduse product evaluation to determine the acceptability. --

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