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America

CERTIFICATE

No. B 17 11 57396 483

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

15641 Red Hill Avenue, Suite 100
Tustin CA 92780
USA

Production Facility(ies): 59319, 71712, 72220, 89850

Certification Mark:

Product: **Power supply**

Model(s): **ECF40USxx**
(where xx can be 12, 15, 18, 24, 28, 36 or 48 designating nominal output voltage)

Parameters:

Rated Input Voltage:	100-240 VAC
Rated Input Current:	1.2 A max
Rated input frequency:	50/60 Hz
Elevation for use:	0-5000 m above sea level
Protection Class:	Class I or Class II at end use
Maximum temperature, ambient:	50°C with 100% rated output 70°C with 50% rated output

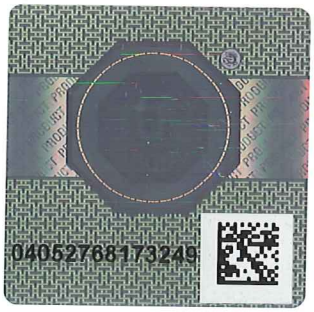
See attachment for output ratings and Conditions of Acceptability.

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.: 095-72132845-000

Valid until: 2022-11-08



Date, 2017-11-16

America

ATTACHMENT TO CERTIFICATE NO. B 17 11 57396 483 FOR XP POWER LLC

POWER SUPPLY

General Product information:

Models covered are open frame power supplies intended for building-in to be used with Medical Electrical Equipment. Units are intended for used with Class I or Class II end-products.

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Approved models and Rated Outputs:

Model Number	OUTPUT RATING		
	Voltage (VDC)	Max Current (A)	Max Power (W)
ECF40US12	10.1-13.5	3.34	40
ECF40US15	13.6-17	2.67	40
ECF40US18	17.1-21	2.23	40
ECF40US24	21.1-26	1.67	40
ECF40US28	26.1-31	1.43	40
ECF40US36	33.1-42	1.11	40
ECF40US48	42.1-54	0.83	40

Conditions of Acceptability:

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

The models require:

- Suitable Mechanical, Fire and Electrical enclosure shall be provided in the end use equipment.
- Proper bonding to the end-product main protective earthing termination is required when the power supply is installed in a Class I end product. 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.
- This power supply was evaluated with Two MOPP between Primary and Secondary for 354Vpk/240Vrms; One MOPP primary and Earth for 350Vpk/240Vrms; One MOPP between Secondary to Ground for working voltage of 48Vdc.
- 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).
- Protective earthing testing shall be conducted in the end product application.
- 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).
- 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).