



America

CERTIFICATE

No. B 17 01 57396 469

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



15641 Red Hill Avenue, Suite 100
Tustin CA 92780
USA

Production
Facility(ies):

59061, 59319, 71712, 89850

Certification Mark:



Product:

Power supply

Model(s):

N12-MMMM-PPFNN

(Where M can be blank or a letter A-Z, indicating module designation; where P can be any number 0-9 or blank for Parallel option codes; where F can be A or C; N can be any number 0-9 or blank for other option codes; "-" provided optionally)

Parameters:

Rated Input Voltage:	100-240 V AC
Rated Frequency:	50/60 Hz
Rated Input Current:	10 A
Rated Output Voltage:	See attachment for out output module ratings and conditions of acceptability
Protection Class:	I at end use
Elevation for use:	0- 3000 m above sea level
Temperature, Ambient:	50°C with 100% rated output power 70°C with 50% rated output power

Tested according to: EN 60601-1:2006/A12:2014

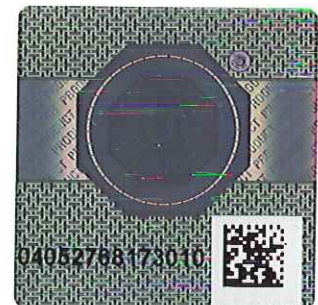
The product was tested on a voluntary basis and complies with the essential requirements. The certification mark shown above can be affixed on the product. It is not permitted to alter the certification mark in any way. In addition the certification holder must not transfer the certificate to third parties. See also notes overleaf.

Test report no.: 095-72123513-000

Valid until: 2022-01-29

Date, 2017-01-31

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POWER SUPPLY

The model covered in this Report is a modular component switching power supply intended for building-in to Medical Equipment.

The power supply consists of an input power platform and various plug-in output modules. Each plug-in output module is one slot width. Each power platform supports four slots per platform.

Outputs can be connected in series or in parallel.

Power Platform Chassis:

N12: Max 850 W (100-180 V), Max 1200 W (180-240 VAC): up to four output modules provided.

Output Module Ratings:

Modules NANO A-E*: 3.3 to 5.5 Vdc, 40 A max, 200 W max.

Modules NANO F-J : 8 to 15 Vdc, 20.8 A max, 250 W max.

Modules NANO K-O: 18 to 30 Vdc, 12.5 A max, 300 W max.

Modules NANO P-T: 33 to 60 Vdc, 6.25 A max, 300 W max.

*: B=blank, no module provided.

Conditions of Acceptability:

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

These models require:

- A suitable electrical and fire enclosure shall be provided in the end use equipment.
- Proper bonding to the end-product main protective earthing terminal is required when the power supply is installed in the end product.
- When installed in end product, the clearance and creepage distance between the hazardous circuitry and accessible parts shall meet the standard(s) requirements. Hi-pot test, leakage current test and ground bond test shall be conducted at end product.
- This power supply was evaluated with Two MOPP between Primary and Secondary; One MOPP primary and Earth.
- Connectors are suitable for factory wiring only.
- Input terminal blocks, when provided, are suitable for No. 12-22 AWG, CU. Appliance Inlet, when provided, does not form the supply connection to ME Equipment.
- 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).

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- Secondary output circuits of module F-T are at hazardous energy level, additional compliance at end use.
- Consideration shall 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.
- The component shall be considered for compliance with the Marking (clause 7) and Separation (clause 8) requirements as part of the end use application evaluation.
- 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).