

# CERTIFICATE No. B 11 09 57396 110

No. B 11 09 57396 110				
Holder of Certificate:	<b>XP Power LLC.</b> 1241 East Dyer Road, Suite 150 Santa Ana CA 92705 USA			
Production Facility(ies):	71712, 59319			
Certification Mark:	SUD SUD			
Product:	Switching power supply unit (Switching Power Supply)			
Model(s):	MHP650PSXXYY, (where XX may be number 12 to 48 indicating main output voltage, YY may be EF, TF or blank for different fan and top cover options)			
Parameters:	Rated Input Voltage:100-240 VAC,Rated Frequency:50/60 HzRated Input Current:9 ARated Output Ratings:See attachmentProtection Class:Class I at end useElevation for use:0-3000 m above sea levelTemperature, Ambient:50°C with full load, 70°C with half load.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.

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## ATTACHMENT TO CERTIFICATE NO. B 11 09 57396 110 FOR XP POWER LLC

## SWITCHING POWER SUPPLY

Models covered in this report are component power supplies intended for use in Medical Electrical Equipment. They are open frame power supplies intended for building-in Class I end product.

#### Approved models:

MHP650PSXXYY DC output	rating:		
Model Number	V (V/A)		Output Dower (MA)
	V	A	Output Power (W)
MHP650PS12YY	12	50	607
MHP650PS15YY	15	40	607
MHP650PS24YY	24	27	657
MHP650PS28YY	28	23	651
MHP650PS36YY	36	18	657
MHP650PS48YY	48	13.5	657

All models are provided with Fan Supply connection (12Vdc, 0.5A) and Standby connection (5Vdc, 0.2A)

#### Model Differences:

The power supplies in the series are differentiated by the output voltage and current ratings, number of turns of primary/secondary winding in the power transformer (T302), type of Fan Chassis top cover and minor differences in the secondary circuit components and printed wiring board (PWB) Layout.

#### Models provide with the YY optional differ as follows:

Model MHP650PSXXEF provided with top cover with fan located at the end of the power supply chassis. Model MHP650PSXXTF provided with top cover with fan located at the top of the power supply chassis. Model MHP650PSXX not provided with top cover and no fan, only provide with U-shaped chassis.

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## ATTACHMENT TO CERTIFICATE NO. B 11 09 57396 110 FOR XP POWER LLC

#### **Conditions of Acceptability:**

- 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 component shall be installed in compliance with the enclosure, marking and separation requirements of the end use application.
- 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 factory wiring inside the end-use product.
- The component shall be installed in compliance with the enclosure, mounting, marking, spacing, and separation requirements of the end use application.
- The power supplies have not been evaluated for use in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.
- Unit not provided with a fan was evaluated with 5m/s airflow across the unit.
- 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
  - Flammable Anaesthetic Mixtures Protection: Annex G

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# CERTIFICATE

No. B 12 01 57396 130

Holder	of Certificate:	

XP Power LLC. 1241 East Dyer Road, Suite 150 Santa Ana CA 92705

Production Facility(ies):

71712, 59319

USA

**Certification Mark:** 



Product:

Model(s):

MHP1000PSXX (where XX may be number 12 to 48 indicating main output voltage)

**Parameters:** 

Rated Input Voltage:100-240 VACRated Frequency:50/60 HzRated Input Current:13 ARated Output Ratings:See attachmentProtection Class:Class I at end useTemperature, Ambient::50°C with full load,70°C with half load.

Switching power supply unit (Switching Power Supply)

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.

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## ATTACHMENT TO CERTIFICATE NO. B 12 01 57396 130 FOR XP POWER LLC

### SWITCHING POWER SUPPLY

Models covered in this report are component power supplies intended for use in Medical Electrical Equipment. They are open frame power supplies intended for building-in Class I end product.

Approved models:

	MHP1000PSXX DC	output rating:	
Model Number	V (V/A)		Output Power (W)
	V	А	
MHP1000PS12	12	83	1001
MHP1000PS15	15	67	1010
MHP1000PS24	24	42	1013
MHP1000PS24 (for input 180-240 V)	24	50	1200
MHP1000PS28	28	36	1013
MHP1000PS28 (for input 180-240 V)	28	40	1204
MHP1000PS36	36	28	1013
MHP1000PS36 (for input 180-240 V)	36	33	1188
MHP1000PS48	48	21	1013
MHP1000PS48 (for input 180-240 V)	48	25	1200
All models are provided v	vith Fan Supply connection (1	2Vdc, 0.5A) and Stand	by connection (5Vdc, 0.2A)

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## ATTACHMENT TO CERTIFICATE NO. B 12 01 57396 130 FOR XP POWER LLC

#### 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 output connectors are not acceptable for field connections, they are only intended for connection to mating connectors of the end use equipment.
- Proper bonding to the end-product main protective earthing terminal is required when the power supply is installed 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

Flammable Anesthetic Mixtures Protection: Annex G

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