ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

C E R T I F I C A T E

No. B 057396 0937 Rev. 00

Holder of Certificate: **XP Power LLC.**
340 Commerce, Suite 100
Irvine CA 92602
USA

Certification Mark:

Product: **Converter**
(DC / DC Converter)

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. This certificate is valid until the listed date, unless it is cancelled earlier.
All applicable requirements of the testing and certification regulations of TÜV SÜD Group have to be complied. For details see: www.tuvsud.com/ps-cert

Test report no.: 7191316975-TR

Valid until: 2028-12-17

Date, 2023-12-21

(Yager Bi)

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Product Service

C E R T I F I C A T E

No. B 057396 0937 Rev. 00

Model(s):

JHM30xxS05
JHM30xxS12
JHM30xxS15
JHM30xxD05
JHM30xxD12
JHM30xxD15
where xx = input DC voltage (12, 24 or 48)

Brand Name: XP Power

Parameters:

Input:
9-18 Vdc, 4A
18-36 dc, 2A
36-75Vdc, 1A

Output:

MODEL	V1		V2		Power
	V	mA	V	mA	W
JHM30xxS05	5	6000			30
JHM30xxS12	12	2500			30
JHM30xxS15	15	2000			30
JHM30xxD05	5	3000	5	3000	30
JHM30xxD12	12	1250	12	1250	30
JHM30xxD15	15	1000	15	1000	30

where xx = input DC voltage (12, 24 or 48)
S = Single output voltage (V1)
D = Dual output voltage (V1 & V2)

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Product Service

C E R T I F I C A T E

No. B 057396 0937 Rev. 00

General product information and other remarks:

- JHM30 is the model series main name followed by xx which denotes the input DC voltage 12 (9 to 18), 24 (18 to 36) or 48 (36 to 75); followed by S (Single Output type) or D (Dual Output type) and followed by the output voltage type (either 05, 12 or 15).
- The product is a build-in component (DC-DC Converter) to be used as part of Medical Electrical Equipment or Power Supply and is intended to provide 2 MOPP (Means of Patient Protection) between the DC input to DC output circuit.

  The unit is provided with top and bottom plastic enclosure. All components inside the unit are mounted on the 2 Printed Wiring Board (PWB); and potted in the plastic enclosure.
- All the varying models differ in input voltage range, output type and regulated output voltage. All models utilize the same components with minor changes to passive components to accomodate the varying voltage and current values.
- The power supply is evaluated as a component of medical device, full compliance shall be evaluated in end product.
- The risk management requirements of the standard were not addressed.

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

- The need for the following shall be considered in the end-product : - Clause 7 for Marking and Accompanying documents evaluation, - Clause 8.7 for Leakage current evaluation, - Clause 9 for Mechanical hazards, - Clause 10 for Radiation hazards, - Clause 11 for excessive temperature and other hazards, - Clause 12 for accuracy of controls, - Clause 14 for Programable Electrical Medical Systems , - Clause 15 for Mechanical Strength, - Clause 16 for ME Systems, The end product configuration should provide proper installation and operation instructions in the, accompanying documents or technical description documents; and these should include Input/Output, ratings and maximum operation ambient conditions. , Installation instructions and equipment markings related to safety will be in a language acceptable in the country in which the equipment is to be installed, The product is not intended to be field serviced or repaired; and shall be installed in compliance with proper enclosure, mounting with adequate clearances and creepages. Insulation is to be re-evaluated during end product configuration., The product is to be installed with stable power source as the 90% and 110% input voltage were not, considered during evaluation., Disconnecting device is to be provided in end product configuration., Considerations to the applied parts requirement shall be evaluated in the end-product. The output circuits have not been evaluated for direct patient connection (Type B, BF or CF)., The electrical, fire and mechanical enclosure requirements of the Standard are to be considered at end, product evaluation as the product has been evaluated as a build-in component., The product was evaluated with 2 MOPP (Means of Patient Protection) based upon manufacturer, declaration of 250Vrms, 354Vpk working voltage; between Primary (Input) to Secondary (Output) circuit. , The insulation system classification of the transformer (T101) is Class B., The core of the Transformer (T101) was evaluated as Primary. The plastic enclosure does not serve as electrical insulation., The accessibility of input pins, output pins, plastic housing/enclosures and the effect of temperatures shall be re-evaluated in the end product., The remote pin functionality is not evaluated in the investigation and suitability is to be determined in the end product application., Temperature Test was conducted without Test Corner. End product to determine the acceptability of risk in conjunction to temperature testing without test corner as part of the power supply., As a component, the application of essential performance, collateral and particular standards are expected on the end-product evaluation.
- Creepage and clearance distances were based on a maximum working voltage of : 250Vrms, 354Vpk as per manufacturer declaration for 2 MOPP between Input and Output, Actual maximum working voltage of T101 primary to secondary: 108.7Vrms, 225.0Vpk, The product

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Product Service

C E R T I F I C A T E

No. B 057396 0937 Rev. 00

outputs have energy < 240VA according to 8.4.2c and have been evaluated across 10kohm resistor to protective earth as per IEC60601-1 (ed3.2) requirements.

- The unit is considered acceptable for use in a max ambient of : -40 to 80°C, 0 to 95% RH (non-condensing) and 54 (5000m altitude) to 106kPa.
- The product has been evaluated as a built-in DC-DC converter intended to be used with medical power supplies in continuous operation. The evaluation does not cover the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
- The product has not been investigated for the protection against hazards of explosions in medical application environment.
- End product is expected to be equipped with suitable protective device as per Clause 8.11.5 in terms of breaking capacity.In the evaluation of this product (DC-DC converter), the following external fuses are installed at both the inputs (+Vin, -Vin): 6.3A for JHM3012xxx, 3.15A for JHM3024xxx and 2A for JHM3048xxx. Fuses did not open during the investigation.
- The product was evaluated for humidity conditioning (Clause 5.7) using 168h instead of 48h as per manufacturer request.

Tested according to: EN 60601-1:2006/A2:2021

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®