



Declaration of Conformity

For the following equipment :

Product Name: Medical Type Switching Power Supply

Model Designation: RPS-120-x (x=12,15,24,27,48); RPS-120-x-C (x=12,15,24,27,48)

is herewith confirmed to comply with the requirements set out in the Council Directive 93/42/EEC concerning Medical devices, the following standards were applied :

RoHS Directive (2011/65/EU), (EU)2015/863

MDD Directive (93/42/EEC)

EN60601-1:2006+A11+A1+A12

TUV certificate No : TA50336473 (RPS-120-x)

EN60601-1:2006+A11+A1+A12

TUV certificate No : TA50335081 (RPS-120-x-C)

EMI (Electro-Magnetic Interference)

Conducted emission / Radiated emission

EN55011:2016+A1:2017

Class B

Harmonic current

EN61000-3-2:2014

Voltage flicker

EN61000-3-3:2013

EMS (Electro-Magnetic Susceptibility)

EN60601-1-2:2015

ESD air

EN61000-4-2:2009

Level 4

15KV

ESD contact

EN61000-4-2:2009

Level 4

8KV

RF field susceptibility

EN61000-4-3:2006+A1:2008+A2:2010

Level 3

10V/m(80MHz-2.7GHz)

RF field susceptibility

EN61000-4-3:2006+A1:2008+A2:2010

Table 9

9~28V/m (385MHz~5.78GHz)

EFT bursts

EN61000-4-4:2012

Level 3

2KV/100KHz

Surge susceptibility

EN61000-4-5:2014

Level 4

2KV/Line-Line

Surge susceptibility

EN61000-4-5:2014

Level 4

4KV/Line-Earth

Conducted susceptibility

EN61000-4-6:2014

Level 3

10V

Magnetic field immunity

EN61000-4-8:2010

Level 4

30A/m

Voltage dip, interruption EN61000-4-11:2004 100% dip 1 periods 30% dip 25 periods 100% interruptions 250 periods

Note:

A component power supply with load will be installed into final equipment which consists of an electronically shielded metal enclosure. Since EMC performance will be affected by the complete installation, the final equipment manufacturers must re-qualify EMC Directive on the complete installation again.

The EMC tests mentioned above are performed using a well defined metal plate to simulate said metal enclosure.

For guidance on how to perform these EMC tests, please refer to "EMI testing of component power supplies".(as available on <http://www.meanwell.com>)" and TDF (Technical Documentation File).

This Declaration is effective from serial number EB9xxxxxx

Person responsible for marking this declaration :

MEAN WELL Enterprises Co., Ltd.

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Johnny Huang/ Manager, Certification Center :

(Name / Position)

(Signature)

Alex Tsai/Director, Marketing Department :

(Name / Position)

(Signature)

Taiwan

(Place)

Jul. 22nd, 2019

(Date)