



Declaration of Conformity

For the following equipment :

Product Name: Switching Power Supply

Model Designation: RPS-400-X-Y(X=12;15;18;24;27;36;48. Y=blank,-C,-SF, -TF)

is herewith confirmed to comply with the requirements set out in the Council Directive, the following standards were applied :

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

MDR Directive (EU) 2017/745

EN 60601-1:2006+A11+A1+A12

TUV certificate No : TA 50430169

MDR Directive (EU) 2017/745

EN 60601-1-2:2015

EMI (Electro-Magnetic Interference)

Conducted emission / Radiated emission

EN 55011:2016+A2:2021

Class B

Harmonic current EN IEC 61000-3-2:2019+A1:2021

Voltage flicker EN 61000-3-3:2013+A1:2019

EMS (Electro-Magnetic Susceptibility)

EN 60601-1-2:2015

ESD air EN 61000-4-2:2009 Level 4 15KV

ESD contact EN 61000-4-2:2009 Level 4 8KV

RF field susceptibility EN IEC 61000-4-3:2020 Level 3 10V/m(80MHz-2.7GHz)

RF field susceptibility EN IEC 61000-4-3:2020 Table 9 9~28V/m (385MHz~5.78GHz)

EFT bursts EN 61000-4-4:2012 Level 3 2KV/100KHz

Surge susceptibility EN 61000-4-5:2014+A1:2017 Level 4 2KV/Line-Line

Surge susceptibility EN 61000-4-5:2014+A1:2017 Level 4 4KV/Line-Earth

Conducted susceptibility EN 61000-4-6:2014 Level 3 10V

Magnetic field immunity EN 61000-4-8:2010 Level 4 30A/m

Voltage dip, interruption EN IEC 61000-4-11:2020 0% residual voltage for 0.5 cycles, 0% residual voltage for 1 cycles, 70% residual voltage for 25 cycles, 0% residual voltage for 250 cycles

Note:

A component power supply will be installed into final equipment. Since EMC performance will be affected by the complete installation, the final equipment manufacturers must re-qualify EMC Directive on the complete installation again. For guidance on how to perform these EMC tests, please refer to TDF (Technical Documentation File)..

The product under declaration is just a unit without medical function. Complete MDR should only be verified when it is used together with particular medical device(s).

This Declaration is effective from serial number SC1xxxxxxx

Person responsible for marking this declaration :

MEAN WELL Enterprises Co., Ltd.

(Manufacturer Name)

No.28, Wuquan 3rd Rd., Wugu Dist., New Taipei City 24891, Taiwan

(Manufacturer Address)

Aries Jian/ Director, Group R&D :

Aries

Alex Tsai/Director, Product Strategy Center :

[Signature]

(Name / Position)

(Signature)

(Name / Position)

(Signature)

Taiwan

October 22, 2021

(Place)

(Date)