Declaration of Conformity

For the following equipment：

Product Name: Medical Type Switching Power Supply

Model Designation:RPS-120S-x (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

MDR Directive (EU) 2017/745

EN60601-1:2006+A1+A12+A2 TUV certificate No：TA50433767

EN 60601-1-2:2015+A1:2021

EMI (Electro-Magnetic Interference)		
Conducted emission	EN 55011:2016+A2:2021	Class B
Radiated emission	EN 55011:2016+A2:2021	Class A(for ClassⅡ)；Class B(for ClassⅠ)
Harmonic current	EN IEC 61000-3-2:2019+A1:2021	
Voltage flicker	EN 61000-3-3:2013+A1:2019+A2:2021	
EMS (Electro-Magnetic Susceptibility)		
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%residualvoltage 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 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).

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 SC3xxxxxxx

Person responsible for marking this declaration：

MEAN WELL Enterprises Co., Ltd.

(Manufacturer Name)

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(Manufacturer Address)

Aries Jian/Director, Group R&D： Aries (Signature)

(Name / Position)

Alex Tsai/Director, Product Strategy Center： (Signature)

(Name / Position)

Taiwan (Place)

Dec. 27th, 2023 (Date)

Version：2