



### Declaration of conformity

For the following equipment :

Product Name: Medical Type Switching Power Supply

Model Designation: RPS-65-x(x=3.3, 5, 7.5, 12, 15, 24 or 48)

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

#### MDD Directive (93/42/EEC)

EN60601-1:2006+A11+A1+A12

TUV certificate No : TA 50328876

#### 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: 2010 | Level 3             | 10V/m(80MHz-2.7GHz)                                 |
| RF field susceptibility   | EN61000-4-3: 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                                       |
| 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:

The power supply is considered as a component that will be operated in combination with final equipment. Since EMC performance will be affected by the complete system, the final equipment manufacturers must re-qualify EMC Directive on the complete system again.

For guidance on how to perform these EMC tests, please refer to TDF (Technical Documentation File).

This Declaration is effective from serial number EB9xxxxxxx

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)

Johnny Huang/Senior Verification Engineer:

(Name / Position)

(Signature)

Alex Tsai/Director, Marketing Department:

(Name / Position)

(Signature)

Taiwan

(Place)

Jul. 22nd, 2019

(Date)