# Declaration of Conformity

For the following equipment：

Product Name: Medical Type Switching Power Supply

Model Designation: RPS-200-12, RPS-200-15, RPS-200-24, RPS-200-27, RPS-200-48, RPS-200-X(X=12,15,24,27,48)

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**

**MDR Directive (EU) 2017/745**

EN 60601-1:2006+A1+A12+A2 — TUV certificate No： TA 50347614 for RPS-200-x-C, TA 50348281 for RPS-200-x

**MDR Directive (EU) 2017/745**

EN 60601-1-2:2015

| | | | |
|---|---|---|---|
| **EMI (Electro-Magnetic Interference)** | | | |
| Conducted emission | EN 55011:2016+A11:2020 | Class B | |
| Radiated emission | EN 55011:2016+A11:2020 | Class A(for Class II),Class B(for Class I) | |
| 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 61000-4-3:2020 | Level 3 | 10V/m(80MHz-2.7GHz) |
| RF field susceptibility | EN 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 3 | 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).

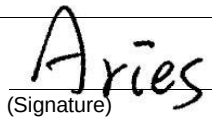
This Declaration is effective from serial number SC3xxxxxxx

Person responsible for marking this declaration：

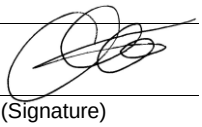
Mean Well Enterprises Co., Ltd.
(Manufacturer Name)

No.28, Wuquan 3rd Rd., Wugu Dist., New Taipei City 24891, Taiwan
(Manufacturer Address)

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


(Signature)

Alex Tsai/Director, Product Strategy Center：
(Name / Position)


(Signature)

Taiwan
(Place)

Nov. 30th, 2023
(Date)