# UK 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, 48)

The designated product(s) is(are) in conformity with the relevant legislation:

**The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012:** SI 2012 No. 3032

**Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)**

BS EN 60601-1:2006+A1+A12+A2 TUV certificate No：TA 50328876

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

**EMI (Electro-Magnetic Interference)**

Conducted emission / Radiated emission

| | | |
|---|---|---|
| | BS EN 55011:2016+A2:2021 | Class B |
| Harmonic current | BS EN 61000-3-2:2019+A1:2021 | |
| Voltage flicker | BS EN 61000-3-3:2013+A1:2019+A2:2021 | |

**EMS (Electro-Magnetic Susceptibility)**

BS EN 60601-1-2:2015+A1:2021 BS EN IEC 61000-6-2:2019

| | | | |
|---|---|---|---|
| ESD air | BS EN 61000-4-2:2009 | Level 4 | 15KV |
| ESD contact | BS EN 61000-4-2:2009 | Level 4 | 8KV |
| RF field susceptibility | BS EN IEC 61000-4-3:2020 | Level 3 | 10V/m(80MHz-2.7GHz) |
| RF field susceptibility | BS EN IEC 61000-4-3:2020 | Table 9 | 9~28V/m (385MHz~5.78GHz) |
| EFT bursts | BS EN 61000-4-4:2012 | Level 3 | 2KV/5KHz |
| Surge susceptibility | BS EN 61000-4-5:2014+A1:2017 | Level 4 | 2KV/Line-Line |
| Conducted susceptibility | BS EN 61000-4-6:2014 | Level 3 | 10V |
| Magnetic field immunity | BS EN 61000-4-8:2010 | Level 4 | 30A/m |
| Voltage dip, interruption | BS 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:**

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).

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：**

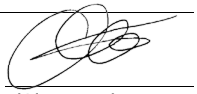
MEAN WELL Enterprises Co., Ltd.
(Manufacturer Name)

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)

Dec. 4th, 2023
(Date)

Version：3