



## UK Declaration of Conformity

For the following equipment :

Product Name: Medical Type Switching Power Supply

Model Designation: MSP-200-x (x=3,3,5,7,5,12,15,24,36,48)

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+A2:2021

CB certificate No : DK-148893-UL

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 IEC 61000-3-2:2019

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

### EMS (Electro-Magnetic Susceptibility)

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/100KHz

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

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

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 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).

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)

*Aries*  
(Signature)

Alex Tsai/ Director, Product Strategy Center :

(Name / Position)

*[Signature]*  
(Signature)

Taiwan

(Place)

Dec. 27th, 2023

(Date)