



UK Declaration of Conformity

For the following equipment :

Product Name: Medical Type Switching Power Supply

Model Designation:MSP-100-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-148724-UL

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

EMI (Electro-Magnetic Interference)

Conducted emission / Radiated emission

BS EN 55011:2016/A2:2021 (Group 1) 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-Line4KV/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 numberSC3xxxxxxx

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. 22th, 2023

(Date)