



# UK Declaration of Conformity

For the following equipment :

Product Name: AC/DC Medical Adaptor

Model Designation:GSM90Ax (x=12,15,19,24,48)

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 50341433

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

### EMI (Electro-Magnetic Interference)

Conducted emission / Radiated emission

BS EN 55011:2016+A2:2021

BS EN IEC 61024-3:2018

Class B

Harmonic current

BS EN IEC 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 61204-3:2018

ESD air

BS EN 61000-4-2:2009

Level 4

15KV

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 3

1KV/Line-Line

Surge susceptibility

BS EN 61000-4-5:2014+A1:2017

Level 3

2KV/Line-FG

Conducted susceptibility

BS EN 61000-4-6:2014

Level 3

10V

Magnetic field immunity

BS EN 61000-4-8:2010

Level 4

30A/m

BS EN IEC 61000-4-11:2020 0% residual voltage for 0.5 cycles,0% residual voltage for 1 cycles , 40% residual voltage for 10 cycles,70% residual voltage for 25 cycles , 80% residual voltage for 250 cycles , 0% residual voltage for 250 cycles

Voltage dip, interruption

### 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. 12th, 2023

(Date)