UK Declaration of Conformity

For the following equipment：

Product Name: AC/DC Medical Adaptor

Model Designation:GSM160Ax(x=12,15,20,24 or 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 50345678

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 IEC EN61000-4-3:2020	Level 3	10V/m(80MHz-2.7GHz)
RF field susceptibility	BS IEC EN 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
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)

Aries
(Signature)

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

(Signature)

Taiwan
(Place)

Aug. 28th, 2023
(Date)

Version：3