Declaration of conformity

For the following equipment：

Product Name: AC/DC Medical Adaptor

Model Designation: GSM160Ax(x=12,15,20,24 or 48)

is herewith confirmed to comply with the requirements set out in the Council Directive, the following standards were applied：

RoHS Directive (2011/65/EU)、(EU)2015/863

MDR Directive (EU) 2017/745

EN 60601-1:2006+A11+A1+A12 TUV certificate No：TA 50345678

MDR Directive (EU) 2017/745

EN 60601-1-2:2015

EMI (Electro-Magnetic Interference)

Conducted emission	EN 55011:2016+A11:2020	Class B
Radiated emission	EN 55011:2016+A11:2020 EN IEC 61024-3:2018	Class B
Harmonic current	EN IEC 61000-3-2:2019+A1:2021	
Voltage flicker	EN 61000-3-3:2013+A1:2019	

EMS (Electro-Magnetic Susceptibility)

EN 60601-1-2:2015 EN IEC 61024-3:2018

ESD air	EN 61000-4-2:2009	Level 4	15KV
ESD contact	EN 61000-4-2:2009	Level 4	8KV
RF field susceptibility	EN IEC 61000-4-3: 2020	Level 3	10V/m(80MHz-2.7GHz)
RF field susceptibility	EN IEC 61000-4-3: 2020	Table 9	9~28V/m (385MHz~5.78GHz)
EFT bursts	EN 61000-4-4:2012	Level 3	2KV
Surge susceptibility	EN 61000-4-5:2014+A1:2017	Level 3	1KV/Line-Line
Surge susceptibility	EN 61000-4-5:2014+A1:2017	Level 3	2KV/Line-FG
Conducted susceptibility	EN 61000-4-6:2014	Level 3	10V
Magnetic field immunity	EN 61000-4-8:2010	Level 4	30A/m
Voltage dip, interruption	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 SC1xxxxxxx

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： Aries

(Name / Position) (Signature)

Alex Tsai/Director, Product Strategy Center：

(Name / Position) (Signature)

Taiwan

(Place)

Sep 14, 2021

(Date)