



Declaration of conformity

For the following equipment :

Product Name: AC/DC Medical Adaptor

Model Designation: GSM160Bx(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/EN60601-1-11:2015

TUV certificate No : TA 50322411

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 IEC 61024-3:2018 EN 60601-1-2:2015 EN IEC 61204-3:2018

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/100KHz

Surge susceptibility EN 61000-4-5:2014+A1:2017 Level 3 1KV/Line-Line

Conducted susceptibility EN 61000-4-6:2014 Level 3 10V

Magnetic field immunity EN 61000-4-8:2010 Level 4 30A/m

EN IEC 61000-4-11:2020
Voltage dip, interruption 0% residual voltage for 0.5 cycles, 0% residual voltage for 1 cycle, 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 SC1xxxxxx

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)

Sep 14, 2021

(Date)