



Declaration of Conformity

For the following equipment :

Product Name:AC/DC Medical Adaptor

Model Designation:GSM40Bx (x=05,07,09,12,15,18,24,48), GSM60Bx (x=05,07,09,12,15,18,24,48)

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

EN60601-1:2006+A1+A12+A2;

EN60601-1-11:2015+A1

TUV certificate No : TA50292178

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

EMI (Electro-Magnetic Interference)

Conducted emission / Radiated emission

EN55011:2016+A2:2021

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+A2:2021

EMS (Electro-Magnetic Susceptibility)

EN 60601-1-2:2015+A1:2021 EN IEC 61024-3:2018

ESD air

EN61000-4-2:2009

Level 4

15KV

RF field susceptibility

ENIEC 61000-4-3:2020

Level 3

10V/m(80MHz-2.7GHz)

RF field susceptibility

ENIEC 61000-4-3:2020

Table 9

9~28V/m (385MHz~5.78GHz)

EFT bursts

EN61000-4-4:2012

Level3

2KV/5KHz

Surge susceptibility

EN61000-4-5:2014+A1:2017

Level 3

1KV/Line-Line

Conducted susceptibility

EN61000-4-6:2014

Level 3

10V

Magnetic field immunity

EN61000-4-8:2010

Level 4

30A/m

Voltage dip, interruption

ENIEC 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 250cycles

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]

(Signature)

Taiwan

(Place)

Dec. 12th, 2023

(Date)