



Declaration of Conformity

For the following equipment :

Product Name: AC DC Medical Adaptor

Model Designation: GSM40Ax (x=05,07,09,12,15,18,24,48), GSM60Ax (x=05,07,09,12,15,18,24,48)

is herewith confirmed to comply with the requirements set out in the Council Directive 93/42/EEC concerning Medical devices, the following standards were applied :

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

MDR Directive (EU) 2017/745

EN 60601-1:2006+A1+A12+A2

TUV certificate No : TA50262994

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

EMI (Electro-Magnetic Interference)

Conducted emission / Radiated emission

EN 55011:2016+A2:2021

Class B

Harmonic current

EN IEC 61000-3-2:2019

Voltage flicker

EN 61000-3-3:2013+A1:2019

EMS (Electro-Magnetic Susceptibility)

EN 60601-1-2:2015+A1:2021 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 2KV/Line-Earth

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 100% dip 1 periods 30% dip 25 periods 100% interruptions 250 periods

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)

Oct. 27th, 2023

(Date)