



Declaration of Conformity

For the following equipment :

Product Name: AC/DC Medical Adaptor

Model Designation: GSMwxy (w=18,25,36 ; x=B,E ; y=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

EN 60601-1:2006+A11+A1+A12; EN 60601-1-11:2015 TUV certificate No : TA50266669

EMI (Electro-Magnetic Interference)

Conducted emission / Radiated emission

EN 55011:2016/A11:2020

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 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 61000-4-3:2006+A1:2008+A2:2010 Level 3 10V/m(80MHz-2.7GHz)

RF field susceptibility EN 61000-4-3:2006+A1:2008+A2:2010 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

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 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 :

(Name / Position)

Aries
(Signature)

Alex Tsai/Director, Product Strategy Center :

(Name / Position)

[Signature]
(Signature)

Taiwan

(Place)

May. 26th, 2021

(Date)