



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

MDD Directive (93/42/EEC)

EN60601-1:2006+A11+A1+A12

TUV certificate No : TA50262994

EMI (Electro-Magnetic Interference)

Conducted emission / Radiated emission

EN55011:2016+A1:2017

Class B

Harmonic current EN61000-3-2:2014

Voltage flicker EN61000-3-3:2013

EMS (Electro-Magnetic Susceptibility)

EN60601-1-2:2015

ESD air EN61000-4-2:2009 Level 4 15KV

ESD contact EN61000-4-2:2009 Level 4 8KV

RF field susceptibility EN61000-4-3:2006+A1:2008+A2:2010 Level 3 10V/m(80MHz-2.7GHz)

RF field susceptibility EN61000-4-3:2006+A1:2008+A2:2010 Table 9 9~28V/m (385MHz~5.78GHz)

EFT bursts EN61000-4-4:2012 Level 3 2KV/100KHz

Surge susceptibility EN61000-4-5:2014 Level 3 1KV/Line-Line 2KV/Line-Earth

Conducted susceptibility EN61000-4-6:2014 Level 3 10V

Magnetic field immunity EN61000-4-8:2010 Level 4 30A/m

Voltage dip, interruption EN61000-4-11:2004 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).

This Declaration is effective from serial number EB9xxxxxx

Person responsible for marking this declaration :

MEAN WELL Enterprises Co., Ltd.

(Manufacturer Name)

No.28, Wuguan 3rd Rd., Wugu Dist., New Taipei City 24891, Taiwan

(Manufacturer Address)

Johnny Huang/Manager, Certification Center :

(Name / Position)

(Signature)

Alex Tsai/Director, Marketing Department :

(Name / Position)

(Signature)

Taiwan

(Place)

Jul. 22nd, 2019

(Date)