



Declaration of Conformity

For the following equipment :

Product Name: AC/DC Switching Adapter

Model Designation: NGE12xyzzzz, NGE18xyzzzz (x=l, UK, y=05, 09, 12, 15, 18, 24, zzzz=maybe Blank, -, 0-9, A-Z or a-z for market purpose)

The designated product(s) is(are) in conformity with the relevant legislation:

The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012: SI 2012 No. 3032

Electrical Equipment (Safety) Regulations 2016 :

BS EN 62368-1:2014+A11:2017

Dekra Certificate: 35-133375

BS EN 60335-1:2012+A15:2021

Dekra Certificate: 35-134255

BS EN IEC 61558-1:2019 ; BS EN 61558-2-16:2009/A1:2013

Dekra Certificate: 35-134253

MDR Directive (EU) 2017/745 :

BS EN 60601-1:2006+A1+A12+A2:2021 ; BS EN 60601-1-11:2015+A1:2021 Dekra Certificate: 35-134254

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

Electrical Compatibility Regulations 2016 :

EMI (Electro-Magnetic Interference)

Conducted emission BS EN 55032:2015+A1:2020

Radiated emission BS EN 55032:2015+A11:2020

BS EN 55011:2016+A2:2021 Class B

Harmonic current BS EN IEC 61000-3-2:2019+A1:2021 Class A

Voltage flicker BS EN 61000-3-3:2013+A1:2019 Clause 5

EMS (Electro-Magnetic Susceptibility)

BS EN 55035: 2017+A11:2020 BS EN IEC 61204-3:2018

ESD air BS EN 61000-4-2:2009 Level4 15KV

ESD contact BS EN 61000-4-2:2009 Level 4 8KV

RF field susceptibility BS EN IEC 61000-4-3:2020 Level 2 3V/m(0.15MHz~80MHz)

RF field susceptibility BS EN IEC 61000-4-3:2020 Table 9 9~28V/m (385MHz~5.78GHz)

EFT bursts BS EN 61000-4-4:2012 Level 2 1KV

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

Surge susceptibility BS EN 61000-4-5:2014+A1:2017 Level 3 2KV/Line-Earth

Conducted susceptibility BS EN 61000-4-6:2014 Level 2 3V

Magnetic field immunity BS EN 61000-4-8:2010 Level 23A/m

Voltage dip, interruption BS EN IEC 61000-4-11:2020 0% residual voltage for 0.5 cycles , 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 installation, the final equipment manufacturers must re-qualify EMC Directive on the complete installation 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. 29th, 2023

(Date)