



Declaration of Conformity

For the following equipment :

Product Name: AC/DC Switching Adapter

Model Designation: NGE65xyzzzz, NGE45xyzzzz, (x=U,E,I,UK,AU,CN, y=05, 09, 12, 15, 18, 24, 48, 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: 35-134681

BS EN 60335-1:2012+A15:2021

Dekra Certificate: 35-135133

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

Dekra Certificate: 35-135132

Medical Devices Regulations 2002 (SI 2002 No 618) (UK MDR 2002)

BS EN 60601-1:2006+A2:2021 ; BS EN 60601-1-11:2015+A1:2021

Dekra Certificate: 35-134871

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	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 BS EN 60601-1-2:2015+A1:2021		
ESD air	BS EN 61000-4-2:2009	Level 4 15KV
RF field susceptibility	BS EN IEC 61000-4-3:2020	Level 2 3V/m(80MHz~2.7GHz)
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 3 2KV
Surge susceptibility	BS EN 61000-4-5:2014+A1:2017	Level 3 1KV/Line-Line
Conducted susceptibility	BS EN 61000-4-6:2014	Level 2 3V
Magnetic field immunity	BS EN 61000-4-8:2010	Level 4 30A/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).

The Ecodesign for Energy-Related Products and Energy Information (Amendment) (EU Exit) Regulations 2020

This Declaration is effective from serial number SC4xxxxxxx

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)

(Signature)

Alex Tsai/Director, Product Strategy Center :
(Name / Position)

(Signature)

Taiwan

(Place)

Jan. 11th, 2024

(Date)