



Declaration of Conformity

For the following equipment :

Product Name: AC/DC Switching Adapter

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

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

Low Voltage Directive (2014/35/EU) :

EN 62368-1:2014+A11:2017	Dekra Certificate: 35-133375
EN 60335-1:2012+A15:2021	Dekra Certificate: 35-134255
EN IEC 61558-1:2019 EN 61558-2-16:2009/A1:2013	Dekra Certificate: 35-134253

MDR Directive (EU) 2017/745 :

EN 60601-1:2006+A2:2021 ; EN 60601-1-11:2015+A1:2021	Dekra Certificate: 35-134254
EN 60601-1-2:2015+A1:2021	

Electromagnetic Compatibility Directive (2014/30/EU) :

EMI (Electro-Magnetic Interference)

Conducted emission	EN 55032:2015+A1:2020	
Radiated emission	EN 55032:2015+A11:2020	Class B
Harmonic current	EN IEC 61000-3-2:2019+A1:2021	Class A
Voltage flicker	EN 61000-3-3:2013+A1:2019	Clause 5

EMS (Electro-Magnetic Susceptibility)

EN 55035:2017+A11:2020	EN IEC 61204-3:2018	
ESD air	EN 61000-4-2:2009	Level4 15KV
ESD contact	EN 61000-4-2:2009	Level 4 8KV
RF field susceptibility	EN IEC 61000-4-3:2020	Level 2 3V/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
Surge susceptibility	EN 61000-4-5:2014+A1:2017	Level 3 1KV/Line-Line
Conducted susceptibility	EN 61000-4-6:2014	Level 2 3V
Magnetic field immunity	EN 61000-4-8:2010	Level 4 30A/m
Voltage dip, interruption	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).

Energy-Related Products Directive (2009/125/EC) :

Ecodesign requirements for no-load condition electric power consumption and average active efficiency of external power supplies (EU)2019/1782

This Declaration is effective from serial number SC3xxxxxxx

Person responsible for marking this declaration :

MEAN WELL Enterprises Co., Ltd.

(Manufacturer Name)

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(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. 8th, 2023
(Date)