



## 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: 35-135230

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

#### Electromagnetic Compatibility Directive (2014/30/EU) :

##### EMI (Electro-Magnetic Interference)

|                    |                               |          |
|--------------------|-------------------------------|----------|
|                    | EN 55032:2015+A1:2020         |          |
| Conducted emission | EN 55032:2015+A11:2020        |          |
| Radiated emission  | EN 55011:2016+A2:2021         | 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         | Level 4 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  |
|                           | 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 |
| Voltage dip, interruption |                           |  |

##### 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)