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)

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: 35-134681
EN 60335-1:2012+A15:2021	Dekra Certificate: 35-135133
EN IEC 61558-1:2019 EN 61558-2-16:2009/A1:2013	Dekra Certificate: 35-135132

MDR Directive (EU) 2017/745 :

EN 60601-1:2006+A2:2021 ; EN 60601-1-11:2015+A1:2021 EN 60601-1-2:2015+A1:2021	Dekra Certificate: 35-134871

Electromagnetic Compatibility Directive (2014/30/EU)：

EMI (Electro-Magnetic Interference)

Conducted emission	EN 55032:2015+A1:2020 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	EN 60601-1-2:2015+A1:2021
ESD air	EN 61000-4-2:2009	Level4 15KV
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 4 2KV/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).

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)

Version：0