Declaration of Conformity

For the following equipment：

Product Name: AC/DC Switching Adapter

Model Designation: NGE12xyzzzz, NGE18xyzzzz (x=I, 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

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 BS EN 60601-1-2:2015+A1:2021	Dekra Certificate: 35-134254

Electrical Compatibility Regulations 2016：

EMI (Electro-Magnetic Interference)

	BS EN 55032:2015+A1:2020	
Conducted emission	BS EN 55032:2015+A11:2020	
Radiated emission	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 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).

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)

(Signature)

Alex Tsai/Director, Product Strategy Center：

(Name / Position)

(Signature)

Taiwan

(Place)

Dec. 29th, 2023

(Date)

Version：0