



Declaration of Conformity

For the following equipment :

Product Name: Medical Type Switching Power Supply

Model Designation: NMP1K2-aaaaaa-xx(a=C, E, H, K, D or #; x=0~9)C=NMS-240-05, E=NMS-240-12, H=NMS-240-24, K=NMS-240-48, #=Blank, D=NMD-240, #=Blank

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

TUV certificate No : R50417957

MDR Directive (EU) 2017/745

EN 60601-1:2006+A1+A12+A2

TUV certificate No : TA50393544 (for NMP1K2)

TUV certificate No : TA50393494 (for NMS-240&NMD-240)

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

Electromagnetic Compatibility Directive (2014/30/EU) :

EMI (Electro-Magnetic Interference)

Conducted emission / Radiated emission

EN 55011:2016+A2:2021

EN 55032:2015+A11:2020

Class B

Harmonic current EN IEC 61000-3-2:2019

Voltage flicker EN 61000-3-3:2013+A1:2019

EMS (Electro-Magnetic Susceptibility)

EN 55024:2010+A1:2015 EN 60601-1-2:2015+A1:2021 EN 55035:2017+A11:2020

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 3 10V/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/100KHz

Surge susceptibility EN 61000-4-5:2014+A1:2017 Level 4 2KV/Line-Line

Surge susceptibility EN 61000-4-5:2014+A1:2017 Level 4 4KV/Line-Earth

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 100% dip 1 periods 30% dip 25 periods 100% interruptions 250 periods

Note:

A component power supply with load will be installed into final equipment which consists of an electronically shielded metal enclosure. Since EMC performance will be affected by the complete installation, the final equipment manufacturers must re-qualify EMC Directive on the complete installation again.

The EMC tests mentioned above are performed using a well defined metal plate to simulate said metal enclosure.

For guidance on how to perform these EMC tests, please refer to "EMI testing of component power supplies".(as available on <http://www.meanwell.com>) and TDF (Technical Documentation File).

This Declaration is effective from serial number TC3xxxxxxx

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)

Taiwan

(Place)

(Signature)

Oct. 30th, 2023

(Date)

Alex Tsai/Director, Product Strategy Center :

(Name / Position)

(Signature)