



Declaration of Conformity

For the following equipment :

Product Name: Medical Type Switching Power Supply

Model Designation: MSP-200-x (x=3,3,5,7,5,12,15,24,36,48)

is herewith confirmed to comply with the requirements set out in the Council Directive 93/42/EEC concerning Medical devices, the following standards were applied :

RoHS Directive (2011/65/EU), (EU)2015/863

MDR Directive (EU) 2017/745

EN 60601-1:2006+A1:2013+A12:2014+A2:2021

CB certificate No : DK-148893-UL

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

EMI (Electro-Magnetic Interference)

Conducted emission / Radiated emission

EN 55011:2016/A2:2021 (Group 1) Class B

Harmonic current EN IEC 61000-3-2:2019

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

EMS (Electro-Magnetic Susceptibility)

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 4KV/Line-Earth

Conducted susceptibility EN 61000-4-6:2014 Level 3 10V

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>)".

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)

Aries
(Signature)

Alex Tsai/Director, Product Strategy Center :

(Name / Position)

[Signature]
(Signature)

Taiwan

(Place)

Dec. 27th, 2023

(Date)