



## Declaration of Conformity

For the following equipment :

Product Name: Switching Power Supply

Model Designation: LOP-400-x, LOP-500-x, LOP-600-x (x= 12, 15, 18, 24, 27, 36, 48 or 54)

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 TUV certificate No : R50613740 · R50613736

BS EN IEC 61558-1:2019 / BS EN 61558-2-16:2009+A1 TUV certificate No : R50613569 · R50613566

BS EN 60335-1:2012+A11+A13+A14+A2+A15 TUV certificate No : R50613676 · R50613671

**Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)**

BS EN 60601-1:2006+A1+A12+A2 TUV certificate No : R50615035 · R50615036

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

**Electrical Compatibility Regulations 2016 :**

**EMI (Electro-Magnetic Interference)**

Conducted emission / Radiated emission

BS EN 55032:2015+A11:2020 Class A (for Class II), Class B (for Class I)

BS EN 55032:2015+A1:2020

BS EN 55011:2016+A2:2021

BS EN IEC 55014-1:2021

Harmonic current BS EN IEC 61000-3-2:2019+A1:2021

Voltage flicker BS EN 61000-3-3:2013+A1:2019+A2:2021

**EMS (Electro-Magnetic Susceptibility)**

BS EN 55035:2017+A11:2020, BS EN 60601-1-2:2015+A1:2021, BS EN IEC 55014-2:2021

ESD air BS EN 61000-4-2:2009 Level 4 15kV

ESD contact BS EN 61000-4-2:2009 Level 4 8kV

RF field susceptibility BS EN IEC 61000-4-3:2020 Level 3 10V/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/5kHz

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

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

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

Magnetic field immunity BS EN 61000-4-8:2010 Level 4 30A/m

BS EN IEC 61000-4-11:2020 <5% residual voltage for 0.5 cycles, 70% residual voltage for 25 cycles, <5% 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)

Jan. 4th, 2024

(Date)