



Declaration of Conformity

For the following equipment :

Product Name: Medical Type Switching Power Supply

Model Designation: X-10-Y (X=NFM,PM) (Y=3,3,5,12,15,24)

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

MDD Directive (93/42/EEC)

EN60601-1:2006+A11+A1+A12

TUV certificate No : TA50308353

EMI (Electro-Magnetic Interference)

Conducted emission / Radiated emission

EN55011:2016+A1:2017 (Group 1) Class B

Harmonic current EN61000-3-2:2014

Voltage flicker EN61000-3-3:2013

EMS (Electro-Magnetic Susceptibility)

EN60601-1-2:2015

ESD air EN61000-4-2:2009 Level 4 15KV

ESD contact EN61000-4-2:2009 Level 4 8KV

RF field susceptibility EN61000-4-3:2006+A1:2008+A2:2010 Level 3 10V/m(80MHz-2.7GHz)

RF field susceptibility EN61000-4-3:2006+A1:2008+A2:2010 Table 9 9~28V/m (385MHz~5.78GHz)

EFT bursts EN61000-4-4:2012 Level 3 2KV/100KHz

Surge susceptibility EN61000-4-5:2014+A1:2017 Level 4 2KV/Line-Line

Conducted susceptibility EN61000-4-6:2014 Level 3 10V

Magnetic field immunity EN61000-4-8:2010 Level 4 30A/m

Voltage dip, interruption EN61000-4-11:2004+A1:2017 100% dip 1 periods 30% dip 25 periods 100% interruptions 250 periods

Note:

A component power supply will be installed into 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)..

This Declaration is effective from serial number EB9xxxxxxx

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)

Johnny Huang/Manager, Certification Center :

(Name / Position)

(Signature)

Alex Tsai/Director, Marketing Department :

(Name / Position)

(Signature)

Taiwan

(Place)

Jul. 22nd, 2019

(Date)