



Declaration of Conformity

For the following equipment :

Product Name: Medical Type Switching Power Supply

Model Designation: X-05-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

MDR Directive (EU) 2017/745

EN 60601-1:2006+A11+A1+A12

TUV certificate No : TA50220068

EMI (Electro-Magnetic Interference)

Conducted emission / Radiated emission

	EN 55011:2016+A1:2017 (Group 1)	Class B
Harmonic current	EN 61000-3-2:2014	
Voltage flicker	EN 61000-3-3:2013	

EMS (Electro-Magnetic Susceptibility)

EN 60601-1-2:2015

ESD air	EN 61000-4-2:2009	Level 4	15KV
ESD contact	EN 61000-4-2:2009	Level 4	8KV
RF field susceptibility	EN 61000-4-3:2006+A1:2008+A2:2010	Level 3	10V/m(80MHz-2.7GHz)
RF field susceptibility	EN 61000-4-3:2006+A1:2008+A2:2010	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 3	1KV/Line-Line
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 61000-4-11:2004+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)..

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 SC1xxxxxx

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)

May. 26th, 2021

(Date)