Declaration of Conformity

For the following equipment：

Product Name: Medical Type Switching Power Supply

Model Designation: RPXY-160Z (X=D,T) (Y=G or blank) (Z=A,B,C,D) ;RPTy-160a-C (y=G or blank) (a=A,B,C, or D)

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

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

BS EN 60601-1: 2006+A12:2014 TUV certificate No：TA50147896

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

BS EN 60601-1-2: 2015

EMI (Electro-Magnetic Interference)

Conducted emission / Radiated emission

	BS EN 55011:2016+A1:2017		Class B
Harmonic current	BS EN 61000-3-2:2014		
Voltage flicker	BS EN 61000-3-3:2013		

EMS (Electro-Magnetic Susceptibility)

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 61000-4-3: 2006+A1:2008+A2:2010	Level 3	10V/m(80MHz-2.7GHz)
RF field susceptibility	BS EN 61000-4-3: 2006+A1:2008+A2:2010	Table 9	9~28V/m (385MHz~5.78GHz)
EFT bursts	BS EN 61000-4-4:2012	Level 3	2KV/100KHz
Surge susceptibility	BS EN 61000-4-5:2014+A1:2017	Level 3	1KV/Line-Line
Surge susceptibility	BS EN 61000-4-5:2014+A1:2017	Level 3	2KV/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
Voltage dip, interruption	BS EN 61000-4-11:2004+A1:2017	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 SC1xxxxxxx

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)

Jun. 28th, 2021

(Date)

Version：0