



## UK Declaration of Conformity

For the following equipment :

Product Name: Switching Power Supply

Model Designation: GEM18ly-zzz (y=05, 07, 09, 12, 15, 18, 24, 28, 48; zzz=0-9, A-Z or Blank)

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 : TA 50306833

**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 EN55011: 2009+A1:2010	Class B
Harmonic current	BS EN 61000-3-2:2014	Class A
Voltage flicker	BS EN61000-3-3:2013	

### EMS (Electro-Magnetic Susceptibility)

BS EN60601-1-2:2015

ESD air	BS EN 61000-4-2:2009	Level 4	15KV
RF field susceptibility	BS EN 61000-4-3:2006+A2:2010	Level 3	10V/m
EFT bursts	BS EN 61000-4-4:2012	Level 3	2KV
Surge susceptibility	BS EN 61000-4-5:2014+A1:2017	Level 3	1KV/L-N
Conducted susceptibility	BS EN 61000-4-6:2014	Level 2	3Vrms
Magnetic field immunity	BS EN 61000-4-8:2010	Level 4	30A/m
Voltage dip, interruption	BS EN 61000-4-11:2004+A1:2017	>95% dip 0.5 periods, 30% dip 25 periods, >95% interruptions 250 periods	

#### N 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 system, the final equipment manufacturers must re-qualify EMC Directive on the complete system 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 EJxxxxxx B2128R

#### 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)

Alex Tsai /Director, Marketing Department :

(Name / Position)

(Signature)

Taiwan

Jul. 1st.2021

(Place)

(Date)