UK Declaration of Conformity

For the following equipment：

Product Name: Switching Power Supply

Model Designation: GEM12Iyzzzzz,GSM12Eyzzzzz (y=05, 07, 09, 12, 15, 18, 24, 28, 48; zzzzz=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 62368-1:2014+A11 TUV certificate No：TA 50371281

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 EN 55024：2010

ESD air	BS EN 61000-4-2:2009	Level 3	15KV
ESD contact	BS EN 61000-4-2:2009	Level 2	8KV
RF field susceptibility	BS EN 61000-4-3:2006+A2:2010	Level 2	10V/m
EFT bursts	BS EN 61000-4-4:2012	Level 2	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		

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 EJxxxxxxx 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)