



### EC-Conformity Declaration

For the following equipment :

Product Name: Switching Power Supply

Model Designation: GEM12lyzzzzz,GSM12Eyzzzzz (y=05, 07, 09, 12, 15, 18, 24, 28, 48; zzzzz=0-9, A-Z or Blank)

is herewith confirmed to comply with the requirements set out in the Council Directive 93/42/EEC concerning Medical devices, 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+A2 TUV Certificate No : TA 50374920

**EMI (Electro-Magnetic Interference)**

Conducted emission	EN55011:2009+A1:2010	CLASS B
Radiated emission	EN55011:2009+A1:2010	CLASS B
Harmonic current	EN61000-3-2:2014	CLASS A
Voltage flicker	EN61000-3-3:2013	

**EMS (Electro-Magnetic Susceptibility)**

EN60601-1-2:2015

ESD air	EN61000-4-2:2008	Level 4	15KV
ESD contact	EN61000-4-2:2008	Level 4	8KV
RF field susceptibility	EN61000-4-3:2010	Level 3	10V/m
EFT bursts	EN61000-4-4:2012	Level 3	2KV
Surge susceptibility	EN61000-4-5:2014	Level 3	1KV / L-N
Conducted susceptibility	EN61000-4-6:2013	Level 2	3Vrms
Magnetic field immunity	EN61000-4-8:2009	Level 4	30A/m
Voltage dip, interruption	EN61000-4-11:2004	>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 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 EJ xxxxxx B2240R

Person responsible for marking this declaration :

Mean Well Enterprises Co., Ltd.

(Manufacturer Name)

No.28, Wuquan 3rd Rd., Wugu Dist., New Taipei City 248, Taiwan

(Manufacturer Address)

Alex Tsai /Director, , Marketing Department :

(Name / Position)

(Signature)

Taiwan

(Place)

Oct.20th.2022

(Date)