



| Declaration of conformity | | | |
|--|-------------------------|----------------------|--|
| For the following equipment: | | | |
| Product Name: Medical Type Switching Power Supply | | | |
| Model Designation: RPS-45-x(x=3.3, 5, 7.5, 12, 15, 24 or 48) | | | |
| is herewith confirmed to comply with the requirements set out in the Council Directive, the following standards were applied : | | | |
| RoHS Directive (2011/65/EU) | | | |
| MDD Directive (93/42/EEC) | | | |
| EN60601-1:2006+A11+A1+A12 TUV certificate No : TA 50328876 | | | |
| EMI (Electro-Magnetic Interference) Conducted emission / Radiated emission | | | |
| | EN55011:2016/A1:2017 | | Class B |
| Harmonic current | EN61000-3-2:2014 | | |
| Voltage flicker | EN61000-3-3:2013 | _ | |
| EMS (Electro-Magnetic Susceptibility) | | | |
| EN60601-1-2:2015 | | | |
| ESD air | EN61000-4-2:2009 | Level 4 | 15KV |
| ESD contact | EN61000-4-2:2009 | Level 4 | 8KV |
| RF field susceptibility | EN61000-4-3: 2010 | Level 3 | 10V/m(80MHz-2.7GHz) |
| RF field susceptibility | EN61000-4-3: 2010 | Table 9 | 9~28V/m (385MHz~5.78GHz) |
| EFT bursts | EN61000-4-4:2012 | Level 3 | 2KV/100KHz |
| Surge susceptibility | EN61000-4-5:2014 | Level 4 | 2KV/Line-Line |
| Conducted susceptibility | EN61000-4-6:2014 | Level 3 | 10V |
| Magnetic field immunity | EN61000-4-8:2010 | Level 4 | 30A/m |
| Voltage dip, interruption | EN61000-4-11:2004 100 % | 6 dip 1 periods 30 9 | % dip 25 periods 100 % 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). | | | |
| This Declaration is effective from serial number EB8xxxxxxx | | | |
| 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) | | | |
| Johnny Huang/Senior Verification Engineer: (Name / Position) Alex Tsai/Director, Marketing Department: (Name / Position) (Signature) (Signature) | | | |

Sep. 17th, 2018

(Date)

Taiwan (Place)