



EC declaration of conformity

For the following equipment :

Product Name: Switching Power Supplies

Model Designation: GSM40Ax (x=05,07,09,12,15,18,24,48), GSM60Ax (x=05,07,09,12,15,18,24,48)

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)

Medical Directive (93/42/EC) :

Low Voltage

EN60601-1:2006

TUV certificate No : TA50262994

EMI (Electro-Magnetic Interference)

Conducted emission / Radiated emission

EN55011:2009+A1:2010 (Group 1)
EN55022:2010
EN61000-6-3:2007+A1:2010
EN61204-3:2000

Class B
Class B

Harmonic current EN61000-3-2:2006

Voltage flicker EN61000-3-3: 2008

EMS (Electro-Magnetic Susceptibility)

EN60601-1-2:2007 EN55024:2010 EN61204-3:2000 EN61000-6-1:2007

ESD air EN61000-4-2:2009 Level 3 8KV

ESD contact EN61000-4-2:2009 Level 2 6KV

RF field susceptibility EN61000-4-3:2006+A1:2008+A2:2010 Level 3 10V/m

EFT bursts EN61000-4-4:2012 Level3 2KV/5KHz

Surge susceptibility EN61000-4-5:2006 Level 4 1KV/Line-Line 2KV/Line-Earth

Conducted susceptibility EN61000-4-6:2009 Level 3 10V

Magnetic field immunity EN61000-4-8:2010 Level 4 3A/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 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 EB3xxxxxxx

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 (R.O.C.)

(Manufacturer Address)

Johnny Huang/Senior Verification Engineer :

(Name / Position)

(Signature)

Ted Cheng/Product Manager :

(Name / Position)

(Signature)

Taiwan

(Place)

Apr. 19, 2013

(Date)