




VERIFICATION OF COMPLIANCE

This Verification of Compliance is hereby issued to the product designated below:

Product **AC/DC MEDICAL ADAPTOR or SWITCHING POWER SUPPLY**

Model **GEM30xyzzzzz & GEM40xyzzzzz**
x can be U,E,AU,UK,AR,KR,CH,I;
y can be 05, 07, 09, 12, 15, 18, 24, 28, 48 ;
z can be 0 to 9, A to Z, hyphen or blank
("U" denotes for American type; "E" denotes for Europe type;
"AU" denotes for 2 Pin Australia type; "UK" denotes for UK type;
"AR" denotes for Argentina type; "KR" denotes for Korea type;
"CH" denotes for china type; "I" detachable plug)

Brand 

Applicant **MEAN WELL ENTERPRISES CO., LTD.**
No.28, Wuquan 3rd Rd., Wugu Dist.,New Taipei City 24891, Taiwan

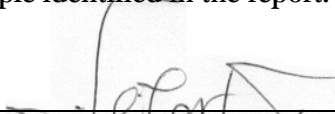
Manufacturer **(1) ELJINTEK, INC.**
6F-1, No.286-3, Shin Ya Road, Chien Chen Dist., Kaohsiung 806 Taiwan
(2) Mean Well Enterprises Co, Ltd
No. 28, Wuquan 3rd Rd.,Wugu Dist.,New Taipei City 248 Taiwan
(3) Mitra Power Solution Co.,Ltd
First Industrial district,Cunwei Village,HengLi Town DongGuan GuangDong PRC.
(4) YOUNGYEAR ELECTRONICS CO LTD
Jin Zhu Industries Area Qing Xi Town Dongguan , Guangdong 523646 China

Applicable Standard(s) **EN 55011: 2009+A1: 2010**
EN 61000-3-2: 2014
EN 61000-3-3: 2013
EN 60601-1-2: 2015
IEC 61000-4-2: 2008, IEC 61000-4-3: 2010,
IEC 61000-4-4: 2012, IEC 61000-4-5: 2014,
IEC 61000-4-6: 2013, IEC 61000-4-8: 2009,
IEC 61000-4-11: 2004

Reference No. **T160810D09-B-E**

Test Laboratory **Compliance Certification Services Inc. (Tainan Lab.)**
No.8, Jiucengling, Xinhua Dist., Tainan City 712, Taiwan (R.O.C.)

This device has been tested and found to comply with the stated standard(s), which is(are) required by the Council Medical Directive & Electromagnetic Compatibility Directive (93/42/EEC ; 2014/30/EU). The test results are indicated in the test report and are applicable only to the tested sample identified in the report.


Jeter Wu / Assistant Manager
Tainan Lab.
Date: October 21, 2016



EC-Declaration of Conformity

The following equipment:

AC/DC MEDICAL ADAPTOR or SWITCHING POWER SUPPLY

(Product Name)

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(Model Designation / Brand Name)

1. ELJINTEK, INC.
2. Mean Well Enterprises Co, Ltd.
3. Mitra Power Solution Co., Ltd.
4. YOUNGYEAR ELECTRONICS CO LTD.

(Manufacturer Name)

1. 6F-1, No.286-3, Shin Ya Road, Chien Chen Dist., Kaohsiung 806 Taiwan
2. No. 28, Wuquan 3rd Rd.,Wugu Dist.,New Taipei City 248 Taiwan
3. First Industrial district,Cunwei Village,HengLi Town DongGuan GuangDong PRC.
4. Jin Zhu Industries Area Qing Xi Town Dongguan , Guangdong 523646 China

(Manufacturer Address)

is herewith confirmed to comply with the requirements set out in the Council Directive on the Approximation of the Laws of the Member States relating to Medical Directive & Electromagnetic Compatibility Directive (93/42/EEC ; 2014/30/EU, Amended by 92/31/EEC, 2006/95/EC & 98/13/EC), For the evaluation regarding the Electromagnetic Compatibility (93/42/EEC ; 2014/30/EU, Amended by 92/31/EEC, 2006/95/EC & 98/13/EC), the following standards are applied:

EN 55011: 2009+A1: 2010

EN 61000-3-2: 2014

EN 61000-3-3: 2013

EN 60601-1-2: 2015

IEC 61000-4-2: 2008, IEC 61000-4-3: 2010,

IEC 61000-4-4: 2012, IEC 61000-4-5: 2014,

IEC 61000-4-6: 2013, IEC 61000-4-8: 2009,

IEC 61000-4-11: 2004

The following manufacturer / importer or authorized representative established within the "EU" is responsible for this declaration:

(Company Name)

(Company Address)

Person responsible for making this declaration:

(Name, Surname)

(Position / Title)

(Place)

(Date)

(Legal Signature)