Vega Technologies Inc.
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Date: October 8th, 2015

EC DECLARATION OF CONFORMITY & REPORT

According to the Medical Device Directive: 93/42/EEC as amended by 2007/47/EC,

The undersigned, Sunny Xie, representing Vega Technologies Inc.,
11F-13,100 Chang-Chun Road, 104 Taipei, Taiwan (office);
Yang Wu District, Da Lang Town, Dong Guan City, Guang Dong Province(factory),
the manufacturer, declares that the equipment described hereafter:

Vega Model No.MT-518 BWC (Dr.Frei Model No T-10)
Vega Model No.MT-518 BWQC (Dr.Frei Model No T-20)
Vega Model No.MT-F19 BSC (Dr.Frei Model No T-30)

Classification *(93/42/EEC (2007/47/EC) (MDD), Annex IX, Section 3, Rule 10, Class IIa)*
GMDN CODE: 34341
European Representative: Biolife, Ltd. 203, Mesogion Av. P.C. 115 25 Athens,
Greece.(VAT NO: EL 999725460)
Country of Origin: China

Provided that it is used and maintained in accordance with the generally accepted codes of good practice and the recommendations of the instructions manual, meets the essential safety and health requirements of the Medical Device Directive.

For the most specific risks of the equipment, safety and compliance with the essential requirements of the Directive has been based on elements of

1. The European Standard EN60601-1:2006/AC:2010-Safety of medical device, Electrical Equipment-General Safety.
2. The European Standard EN ISO14971:2012 Medical devices – Application of risk management to medical devices.
3. The European Standard EN60601-1-2 : 2007/AC:2010 General requirement for Safety-Collateral Standard: Electromagnetic Compatibility-Requirements and tests
4. The ISO 13485:2012/AC2012 Quality Management Systems –Medical Device.
5. The European Standard ISO 9001:2008 Quality Management System-Model for quality assurance in design/development, production, installation, and servicing.
6. ISO 15223-1:2012 Medical devices-Symbols to be used with medical device labels ,labeling and information to be supplied
7. The European Standard EN1041:2008 Information supplied by the manufacturer with medical

devices

8. The European Standard EN 980:2008 Symbols for use in the labeling of medical devices.
9. The European Standard EN12470-3:2000+A1:2009 Clinical thermometers - Part 3: Performance of compact electrical thermometers (non-predictive and predictive) with maximum device
10 The European Standard EN10993-1:2009 /AC:2010 Biological evaluation of medical devices. Evaluation and testing
11 The European Standard EN 60601-1-11:2010 Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
12 The European Standard EN 60601-1-6:2010 Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
13 The European Standard BS EN 62366:2008 Medical devices-Application of usability engineering to medical devices.
14 EN 980:2008 Symbols for use in the labeling of medical devices.

Sincerely Yours,

Vega Technologies Inc.
微格有限公司

Authorized Signature

Rena Fang/Sales executive

Vega Technologies Inc.