



VEGA TECHNOLOGIES INC.

11F-13, 100 CHANG-CHUN ROAD, TAIPEI, TAIWAN

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Http://www.vegamedical.com

EC Declaration of Conformity

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

The undersigned, Mr. Donnie Lee, representing Vega Technologies Inc.,
11F-13,100 Chang-Chun Road, Taipei, Taiwan (office);
Yang Wu District, Da Lang Town, Dong Guan City, Guang Dong Province(factory),
the manufacturer, declares that

For the following products:

Digital Thermometer: MT-P19 (A&D company: UT-113)
*has be assigned to Class IIa according to Annex IX Rule 10 of the Directive 93/42/EEC;
is hereinafter confirmed to comply with the requirements set out in the Council Directive
on the harmonization of the Laws of the Member States concerning Medical Device
Directive (93/42/EEC As amended by 2007/47/EC).*

- EN60601-1:2006/A12:2014; EN ISO14971:2012;
- EN60601-1-2 : 2015; EN ISO13485:2016;
- ISO 9001:2015; EN ISO 15223-1: 2016/CRGD:2017;
- EN1041:2008; EN12470-3:2000+A1:2009;
- EN ISO10993-1:2009 /AC:2010; EN 60601-1-11:2015;
- EN60601-1-6:2010/2015; EN 62366-1:2015/CRGD:2016;
- EN62304:2006/AC:2008/A1:2015 EN ISO 80601-2-56:2017

Conformity Assessment Route:

Annex II excl. section 4 of Medical Device Directive

Notified Body: TÜV Rheinland LGA Products GmbH (CE No. 0197)
Tillystraße 2, 90431 Nürnberg, Deutschland

Registration No.: HD 60134007 0001

Effective date: 2019-01-17 Expiry date: 2024-01-16

The following representative in Europe is responsible for making this declaration:

Company Name: Biolife Ltd.

Company Address: No.332, Kifisias Av., 15235 Halandri, Athens, Greece

The following manufacturer is responsible for making this declaration:

Company Name: VEGA TECHNOLOGIES INC.

Company Address: 11F-13,100 CHANG-CHUN ROAD,TAIPEI, TAIWAN

The Management Representative

March 29, 2019

(Legal Signature)

(Position/title)

(Date)