



**VEGA TECHNOLOGIES INC.**

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

TEL: 886-2-2541-6996 FAX: 886-2-2521-3803

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, Ms. Sunny Xie, 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-N18 (A&D company: UT-103)

*has be assigned to Class IIa according to Annex IX Rule 10 of the Directive 93/42/EEC;  
and are 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

Sunny Xie Sales Manager

August 21, 2019

(Legal Signature)

(Position/title)

(Date)