

# EC Declaration of Conformity

Doc. No.: 【AIQP-003-182】

*Manufacturer:*

**AViTA Corporation**  
9F, NO.78, Sec.1, Kwang-Fu Rd., San-  
Chung, Taipei County, Taiwan, R.O.C.

*whose single Authorized Representative:*

**Wellkang Ltd.,**  
Suite B, 29 Harley Street,  
LONDON W1G 9QR,  
England, United Kingdom

We, the manufacturer, herewith declare that the products

**Product: Ear Thermometer**  
**Avita Model : TS29**

(including system components and accessories)  
meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa Rule 10, 3.2/3rd indent according to Annex IX of the Directive 93/42/EEC. It bears the mark

**CE 0197**

The product concerned has been designed and manufactured under a quality management system according to Annex II, without the Annex II.4, of Directive 93/42/EEC, and the essential requirement of Annex I pertaining to medical devices

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

**TÜV Rheinland LGA Products GmbH**  
**Tillystraße 2**  
**90431 Nürnberg**  
**Country : Germany**

Certificate No.: HD 60099060 0001

Issue date: 2015.03.12

Expiry date: 2020.03.02

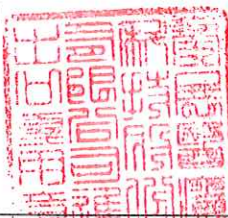

following the procedure relating to the EC Declaration of Conformity set out in Annex II (without the Annex II.4), of Directive 93/42/EEC

The above mentioned declaration of conformity is exclusively under the responsibility of

**AViTA Corporation**

New Taipei City, May 10, 2017

*Place, date*

  
  
*Legally binding signature, Function*