



# EC Declaration of Conformity

APS0-01-050

*Manufacturer:*

**AViTA Corporation**  
9F, No.78, Sec. 1, Kwang-Fu Road, San-Chung  
District, New Taipei City 24158 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: Infrared Thermometer Model: TS8 (SC 53 FH)**

(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 according to Annex IX of the Directive 93/42/EEC. It bears the mark



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) & Annex VII, of Directive 93/42/EEC

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

**AViTA Corporation**

**AVITA CORPORATION**

Taipei County, 23-May-2018

*Place, date*

\_\_\_\_\_  
*Legally binding signature* *Function* *Signature*