

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: Non-contact Thermometer Model: FT85

(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

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

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

AViTA Corporation

New Taipei City, 25-July-2018

Place, date

Legally binding signature, Function