

EC Declaration of Conformity

APS0-01-051

Manufacturer:

whose single Authorized Representative:

AViTA Corporation 9F, No.78, Sec. 1, Kwang-Fu Road, San-Chung District, New Taipei City 24158 Taiwan, R.O.C. MDSS GmbH Schiffgraben 41 30175 Hannover, Germany

We, the manufacturer, herewith declare that the products

Product: Touch Free Infrared Thermometer Model: NT13B

(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 Rule 10, of the Directive 93/42/EEC. It bears the mark

C €0598

The product concerned has been designed and manufactured under a quality management system according to Annex II, excluding sec.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

SGS Fimko Ltd
Takomotie 8
FI-00380 Helsinki, Finland
Notified Body 0598
Country: Finland
Certificate No.: FI20/07003

Issue date: 2020.02.25 Expiry date: 2024.05.24

following the procedure relating to the EC Declaration of Conformity set out in Annex II (excluding sec.4) & Annex VII, of Directive 93/42/EEC

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

AViTA Corporation

AVITA CORPORATION

New Taipei City, 05/12 / 2020 /

David Huang QA Director

Legally binding signature, Function