EC Declaration of Conformity

APS0-01-062

We, the manufacturer, herewith declare that the products

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declare that the medical devices described hereafter

The Product: Infrared Ear/Forehead Thermometer

Model: Infrared Ear/Forehead Thermometer, TS Series
TS8 (SC 53 FH)

The medical device has been assigned to class IIa according to Annex IX Rule 10 of the Directive 93/42/EEC. The product concerned has been designed and manufactured under a quality management system according to Annex II, excluding sec.4 of the Directive 93/42/EEC, and the essential requirement of Annex I pertaining to medical devices. The following standards apply to design and/or manufacturing of the products.

- EN ISO 15223-1:2016 - Medical devices - Symbols to be used with medical devices labels, labelling and information to be supplied - Part 1: General Requirements
- EN 1041:2008+A1:2013 - Information supplied by the manufacturer of medical devices
- EN ISO 10993-1:2018 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- EN ISO 10993-5:2009 - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- EN ISO 10993-10:2013 - Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
- EN ISO 10993-12:2012 - Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials
- EN ISO 13485:2016 - Medical devices - Quality management systems - Requirements for regulatory purposes
- EN ISO 14971:2012 - Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
- EN 60601-1:2006+A1:2013 / IEC 60601-1:2005+A1:2012 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- EN 60601-1-2:2015 / IEC 60601-1-2:2014 - Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-6:2010+A1:2013 - Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability
- IEC 62304:2006+AMD1:2015 - Medical device software - Software life-cycle processes
- EN 62366-1:2015- Medical devices - Application of usability engineering to medical devices
- EN 60601-1-11:2015 / IEC 60601-1-11:2015 - Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance – Collateral Standard:

Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

- EN 50581:2012 - Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances (RoHS)
- EN 50419:2006 - Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2012/19/EU (WEEE)
- EN ISO 80601-2-56:2017 Medical electrical equipment - Part 2-56 Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.
- EN 12470-5:2003 - Clinical thermometers - Part 5: Performance of infra-red ear thermometers (with maximum device)
- ASTM E 1965-98 (Re-approved 2016)
- EN ISO 14155:2011/AC:2011 – Clinical investigation of medical devices for human subject
- EN ISO 17100:2015+A1:2017 - Translation services. Requirements for translation services
- EN ISO 17664:2017- Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices

and are in conformity with the national standards transposing harmonised standards to be determined on the date of this DoC has signed

and are subject to the procedure set out in Annex II of Directive 93/42/EEC under the supervision of the Notified Body SGS Fimko Ltd loacted at: Takomotie 8, FI-00380 Helsinki, Finland
Notified Body Number: 0598
CE Certificate No.: FI20/07003
Issue date: 2021.03.24
Expiry date: 2024.05.24

whose single Authorized Representative:
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The above mentioned declaration of conformity is exclusively under the responsibility of
AViTA Corporation

Legally binding signature, Function
Title: Quality Assurance Director
Name: Christa Huang

Place and date of issue
Taipei,2021/7/6