# EC Declaration of Conformity

APQ0-19-082

We, AViTA Corporation, the manufacturer, herewith declare that the EU declaration of conformity is issued under the sole responsibility of the manufacture compliance with EU Medical Device Regulation 2017/745:

**Manufacture:** AViTA Corporation
**Address:** 9F, No.78, Sec. 1, Kwang-Fu Road, San-Chung District, New Taipei City 24158 Taiwan, China
**SRN code:** TW-MF-000010455

**European Authorised Representative:** Medical Device Safety Service GmbH
**Address:** Schiffgraben 41, Hannover 30175, Germany
**SRN code:** DE-AR-000005430

Product Name: Infrared Ear/Forehead Thermometer

Model number:

| Type | Model | Importer | Type | Model | Importer |
|---|---|---|---|---|---|
| TS12 | TS12 | AViTA | TS53BC | TS53BC | AViTA |
| | 00009903000000 | Artsana | | SFT81_blackline | Beurer |
| TS29 | TS29 | AViTA | TS9 | TS9 | AViTA |
| | TE-150-EU | UPGS | TS15 | TS15 | AViTA |
| | TE-101-EU | Homedics | TS21 | TS21 | AViTA |
| | TE-420-EU | Homedics | TS23 | TS23 | AViTA |
| TS42 | TS42 | AViTA | TS27 | TS27 | AViTA |
| TS42B | TS42B | AViTA | TS27B | TS27B | AViTA |
| TS46 | TS46 | AViTA | TS31 | TS31 | AViTA |
| TS53 | TS53 | AViTA | TS37 | TS37 | AViTA |
| | SFT79 | Beurer | TS45 | TS45 | AViTA |
| TS53B | TS53B | AViTA | TS51 | TS51 | AViTA |
| | SFT81 | Beurer | | AGU SHE10 | Montex |

Intended use: This thermometer is intended for home use and the measurement of human body temperature in people of all ages. This thermometer takes temperatures in seconds by measuring the heat generated by the ear canal/ on the forehead.

Basic UDI-DI: 471095342TCF04TSXN4
EMDN Code: V03010201
Catalogue number: APS0-01-09

The medical device has been assigned to class IIa according to Annex VIII Rule 10 of Regulation (EU) 2017/745. The product concerned has been designed and manufactured under a quality management system according to Annex IX, Regulation(EU) 2017/745, and the general safety and performance requirements of Annex I pertaining to medical devices. The following regulations apply to design and/or manufacturing of the products.

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**Quality management systems or information supplied by Manaufacture**

- EN ISO 15223-1:2021 - Medical devices - Symbols to be used with medical devices labels, labelling and information to be supplied - Part 1: General Requirements
- ISO 20417:2021- Medical devices - Information to be supplied by the manufacturer.
- EN ISO 13485:2016 - Medical devices - Quality management systems - Requirements for regulatory purposes
- EN ISO14971:2019/A11:2021 - Medical devices - Application of risk management to medical devices
- ISO/TR 24971:2020- Medical devices - Guidance on the application of ISO 14971
- ISO/TR 20416:2020- Medical devices — Post-market surveillance for manufacturers
- ISO 14155:2020 –Clinical investigation of medical devices for human subjects — Good clinical practice
- MEDDEV 2.7/1 rev.4 June 2016
- IEC ISO 80601-2-56:2017/A1:2020 Medical electrical equipment - Part 2-56 Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
- EN ISO 17664-1:2021- Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices
- ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices

**ISO 10993 Biocompatibility**

- 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 10993-10:2023 - Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
- EN ISO 10993-12:2021 - Biological evaluation of medical devices - Part 12: Sample preparation and reference materials .
- EN ISO 10993-23:2021- This document specifies the procedure for the assessment of medical devices and their constituent materials with regard to their potential to produce irritation by using an in vitro reconstructed human epidermis model.

**EU compliance for materials**

- RoHS 2.0 (2015/863/EU) and some components require an EU RoHS exemption, the following may apply: 7(c)-I - Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, e.g. piezoelectric devices, or in a glass or ceramic matrix compound.
- REACH Regulation (EC) No 1907/2006 (Registration, Evaluation and Authorization of Chemical Substances) & SVHC (identifying Substances of Very High Concern)
- WEEE (Waste from Electrical and Electronic Equipment ) Directive 2012/19/EU)

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**Electrical Medical Device requirements**

- IEC 60601-1:2006/A2:2021 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2015/A1:2021- Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- IEC 60601-1-11:2015/A1:2021-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.
- IEC 62479:2010 - Assessment of the compliance of low-power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)

**Radio Equipment Directive 2014/53/EU (RED)**

- ESTI EN 301 489-1 V2.2.3(2019-11) - ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard for ElectroMagnetic Compatibility
- ESTI EN 301 489-17 V3.2.4 (2020-09) - ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard for ElectroMagnetic Compatibility
- ESTI EN 300 328 V2.2.2 (2019-07)- Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz band; Harmonised Standard for access to radio spectrum
- IEC 60601-1:2006/A2:2021 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

**Software requirements**

- IEC 62304:2006+AMD1:2015 - Medical device software - Software life-cycle processes

**Usability**

- IEC 62366-1:2015/A1:2020- Medical devices - Application of usability engineering to medical devices
- IEC 60601-1-6:2010+A2:2021 - Medical electrical equipment General requirements for basic safety and essential performance. Collateral standard: Usability.

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 IX of Regulations (EU) 2017/745 under the supervision of the Notified Body: BSI Group The Netherlands B.V.
Notified Body Number: 2797
CE Certificate No.: MDR 775622
Issue date: 2023.03.14
Expiry date: 2028.03.13

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The above mentioned declaration of conformity is issued under the sole responsibility of AVITA Corporation

Legally binding signature, Function
Title: President
Name: Frank Jih

Place and date of issue
Taipei, 2023.07.25

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## Revision History

| Revision No. | Revision Date | Description of revision |
|---|---|---|
| 0 | 2023.3.22 | New release |
| 1 | 2023.5.12 | Due to the Customs of China enforcement, AViTA is requested to the China after the legal manufacturer address on the MDR certificate. |
| 2 | 2023.07.25 | Routine update on the regulation year, also add safety regulation below RED directive due to RED Article 3.1 safety confirmation. |