Declaration of Conformity

APQ0-19-041

We, the manufacturer,

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declare that the medical devices described hereafter

The Product: Touch Free Infrared Thermometer
Infrared Ear/Forehead Thermometer

Model: Touch Free Infrared Thermometer, NT Series
NT11, NT13, NT13B, NT16, NT16B (02009197000000, 02009197100000, 0000922200000)
NT17, NT18, NT19, NT1B, NT1G, NT22, NT23, NT24B, NT36 (SNC10), NT61, NT62, FT85, FT90, FT95, FT100, NT11M, NT66, NT67

Infrared Ear/Forehead Thermometer, TS Series
TS7, TS8, TS9, TS12 (00009903000000), TS14, TS15, TS21, TS23, TS24, TS26, TS27, TS28, TS28B, TS29, TS31, TS37, TS41, TS41S, TS42, TS42B (TM750 Connect, TM755 Connect), TS45, TS46, TS46B, TS47, TS48, TS52 (SFT77), TS51 (SHE10), TS53(SFT79/SFT81), TS36B

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 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 15223-1:2021 - 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.
- 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
- ISO 10993-10:2021 - Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
- ISO 10993-12:2021 - Biological evaluation of medical devices - Part 12: Sample preparation and reference materials .
- 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.
- EN ISO 13485:2016 - Medical devices - Quality management systems - Requirements for regulatory purposes
- ISO 14971:2019 - Medical devices - Application of risk management to medical devices

- 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 60601-1-6:2010+A2:2021 - Medical electrical equipment General requirements for basic safety and essential performance. Collateral standard: Usability.
- 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 62304:2006+AMD1:2015 - Medical device software - Software life-cycle processes
- IEC 62366-1:2015/A1:2020- Medical devices - Application of usability engineering to medical devices
- 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)
- WEEE (Directive 2012/19/EU)
- 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
- ISO 14155:2020 –Clinical investigation of medical devices for human subjects — Good clinical practice
- 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
- 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 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)

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: 2020.02.26
Expiry date: 2024.05.24

Declaration of Conformity

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whose single Authorized Representative:
MDSS GmbH
Schiffgraben 41, 30175 Hannover, Germany
www.mdssar.com

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

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

Place and date of issue
New Taipei, June , 8th , 2022