

EU DECLARATION OF CONFORMITY

(In accordance with EN ISO/IEC 17050-1)

Declaration number: **DOCIP 2051083**

Name and address of manufacturer / EU-AR: **NEDIS
De Tweeling 28
5215 MC 's Hertogenbosch
Netherlands**



THIS DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF:

Name and address of manufacturer: **NEDIS
De Tweeling 28
5215 MC 's Hertogenbosch
Netherlands**

Product identification: **Smart Infrared Thermometer
BTHTIR10WT**



THE PRODUCTS MENTIONED IN THIS DECLARATION ARE IN CONFORMITY WITH:

EU Community Legislation: **Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU [OJEU L174/88-110, 01.07.2011]
Medical Devices Regulation (EU) 2017/745 [OJEU L117/1-175, 05.05.2017]**

Harmonised standards: **Medical devices**
EN 60601-1-11:2015
EN 60601-1:2006 + AC:2010 + A1:2013 + AC:2014 + A12:2014 + A2:2021 + AC:2022-12
EN 62304:2006 + AC:2008 + A1:2015
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 14971:2019 + A11:2021
EN ISO 15223-1:2021

Electromagnetic Compatibility (EMC)
EN 60601-1-2:2015 + A1:2021

Restricted substances in electrical products
EN IEC 63000:2018

Other specifications: **Single registration number: NL-IM-000028061
Risk class: IIa
Basic UDI-DI: 697204011AOJ20X178**

Intended purpose: **The product is intended to measure human body temperature via the eardrum for people over 3 months or via the forehead for people of all ages for professional use or home use**

Notified Body: **TÜV SÜD Product Service GmbH (0123)
Certificates: G2 1037030001
Modules: A**

SIGNED FOR AND ON BEHALF OF:

Place and date of issue: **'s Hertogenbosch, 19 July 2023**

Signature:

A handwritten signature in black ink, appearing to be 'G.M.', written over a horizontal line.

Name, position: **Gard Moors
Compliance & Quality manager Nedis**

Company name: **NEDIS**