Kaz Europe Sàrl
Q-Center, Route de la Chaux 4
CH-1030 Bussigny
Switzerland

EU Declaration of Conformity

We, **Kaz Europe Sàrl**, Q-Center, Route de la Chaux 4, CH-1030 Bussigny, Switzerland declare under our sole responsibility that the product to which this declaration relates is in conformity with the following standard(s) or other normative document(s) and proves the conformity of the designated product with the provisions of the below Regulation(s) and Directive(s):

- **MDR – Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices**
- **RoHS - Directive 2011/65/EU (including (EU) 2015/863) of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment**

Brand Name	Product Name	Reference(s)
Braun	Sensian™ 3 Non-contact thermometer	BNT050WE BNT050EE

Common Specification(s) Applied:

CS Reference	Edition	Title
N/A	N/A	There are no Common Specification applicable to the product

Standards Applied:

Standard Reference	Edition	Title
EN ISO 13485	2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971	2019	Medical devices- Application of risk management to medical devices.
EN 60601-1	2006 + A2:2021	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
EN 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
EN 60601-1-2	2015 + A1:2021	Medical Electrical Equipment – Part 1-2: General requirements for Basic Safety and Essential Performance- Collateral Standard: Electromagnetic Compatibility- Requirements and Tests
EN 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 IEC 62304	2006 + A1:2015	Medical devices - Application of usability engineering to medical devices
EN IEC 60601-1-6	2010 + A1:2015	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
EN IEC 62366-1	2015	Medical devices — Application of usability engineering to medical devices
EN ISO 10993-1	2020	Biological evaluation of medical devices — Part 1: Evaluation and testing.
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 sensitization
EN 15223-1	2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 14155	2020	Clinical investigation of medical devices for human subjects - Good clinical practice

Helen of Troy

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The Technical Documentation is the responsibility of: Kaz Europe Sàrl, Q-Center, Route de la Chaux 4, CH-1030 Bussigny, Switzerland.

Additional information:

For Medical Device Regulation (EU) 2017/745	
Intended Purpose	This non-contact forehead thermometer is a handheld, battery-powered, infrared thermometers intended for the intermittent measurement of human body temperature in a home-use environment on people of all ages, except pre-term and small-for-gestational-age babies, using the center of the forehead as the measurement site. This thermometer is not intended for clinical use in a professional environment and is for home usage only.
Regulatory class (Annex VIII):	Class IIa (Annex VIII rule 10)
Conformity assessment:	The Conformity Assessment Procedure has been performed following Art.19 and Art. 52 (6), following Chapters I and III of Annex IX and including an assessment of Technical Documentation following Annex II and III of the Regulation (EU) 2017/745
Basic UDI-DI	76307593BNT050K4
EMDN nomenclature (CND)	V0301010202
Global /universal nomenclature	GMDN 17888 and UMDNS 14036
EU SRN	CH-MF-000029980
Swiss SRN	CHRN-MF-20000627
Notified Body	DQS Medizinprodukte GmbH August Schanz Str. 21 D-60433 Frankfurt, Germany Registration number: 0297
EU Authorised Representative	Obelis, S.A. Address: Bd. Général Wahis, 53 1030 Brussels, Belgium with SRN BE-AR-000000106
EC Certificate	381008 MDR2017Q
EN ISO 13485 Certificate	381008 MP2016

Revision	Change Description	Approval date
00	Initial Declaration of Conformity under Regulation (EU) 2017/745	See below

This declaration of conformity is valid from July 31, 2024. until July 29, 2029.

Michael Burke General Manager EMEA	Legally binding signature	Maud Giorgi PRRC, Associate QMS & Regulatory Affairs Director EMEA	Legally binding signature

Lausanne	July 31, 2024
Place	Date