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 declares 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	ThermoScan® 3	IRT3030EE IRT3030WE
Braun	ThermoScan® 4	IRT3515EE IRT3515WE

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 + A11:2021	Medical devices- Application of risk management to medical devices.
EN 60601-1	2006 + A1:2013 + A12:2014 + A2:2021 + A13:2024	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 + A2:2021	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
EN IEC 62366-1	2015 + A1:2020	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	2023	Biological evaluation of medical devices — Part 10: Tests for irritation and sensitization
EN ISO 10993-23	2023	Biological evaluation of medical devices — Part 23: Tests for irritation
EN 15223-1	2021	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

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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	The Ear thermometer is intended to be used by home users for intermittent measurement of the body temperature of patients having ages ranging from normal weight (full term) new-born to geriatric adult. The thermometer is reusable.
Regulatory class (Annex VIII):	class IIa (Annex VIII rule 10)
Conformity assessment:	Class IIa: 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	76307593IR3030G5
EMDN nomenclature (CND)	V0301010201
Global /universal nomenclature	GMDN 17887 and UMDNS 17-887
EU SRN	CH-MF-000029980
Swiss SRN (CHRN)	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 • For IRT3030WE under MDR, this declaration of conformity is valid from LOTs 13225fam, 13325fam and 13425fam with manufacturing date May 26, 2025 • For IRT3030EE under MDR, this declaration of conformity is valid from LOT 13525fam with manufacturing date May 23, 2025	June 19, 2025
01	Addition of Braun ThermoScan 4, IRT3515 where all new LOTs are under MDR	October 30, 2025

This declaration of conformity is valid from October 30, 2025 until July 29, 2029

Signed by Mike Burke
Michael Burke
I approve this document
October 30, 2025 | 12:35:38 PM CET
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Signed by Maud Giorgi
Maud Giorgi
I approve this document
October 30, 2025 | 2:14:00 PM CET
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Michael Burke		Maud Giorgi	
General Manager EMEA	Legally binding signature	PRRC, Associate QMS & Regulatory Affairs Director EMEA	Legally binding signature

Bussigny	October 30, 2025
Place	Date