EC Declaration of Conformity

We, **Kaz Europe Sàrl**, Place Chauderon 18, 1003 Lausanne, 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 Directive(s):

- **MDD - Council Directive 93/42/EEC of 14 June 1993 concerning medical devices**
- **RoHS - Directive 2011/65/EU 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**

Name	Type or model
Braun ThermoScan 3 IR Thermometer IRT3030	IRT3030 IRT3030WE IRT3030EE IRT3030LA

Standards Applied:

Standard Reference	Edition	Title
EN 12470-5	2003	Clinical thermometers — Part 5: Performance of infra-red ear thermometers (with maximum device)
ASTM E1965-98	2009	Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature
ISO 80601-2-56	2009	Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.
EN 60601-1	2006 + A1:2013	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
EN 60601-1-2	2015	Medical electrical equipment – part 1-2: General requirements for basic safety and essential performance – Collateral standard: electromagnetic compatibility – Requirements and tests.
IEC 60601-1-4	1996 + A1:1999	Medical electrical equipment – part 1-4: General requirements for safety – Collateral standard: programmable electrical medical systems.
EN 60601-1-6	2010	Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral Standard: Usability.
EN 60601-1-11	2010	Basic safety and essential performance of medical electrical equipment and medical electrical systems which are intended by their manufacturer for use in the home healthcare environment.
EN ISO 14971	2019	Medical devices- Application of risk management to medical devices.
EN ISO 10993-1	2009	Biological evaluation of medical devices — Part 1: Evaluation and testing.
EN 62304	2008	Medical device software – Software life-cycle processes.
EN ISO 15223-1	2016	Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1 – General requirements
EN 1041	2008	Information supplied by the manufacturer with Medical Devices
EN 62366	2008	Medical devices– Application of usability engineering to medical devices

The Technical Documentation is the responsibility of: Kaz Europe Sàrl, Place Chauderon 18, CH-1003 Lausanne, Switzerland

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Additional Information:

For Medical Device Directive 93/42/EC	
Regulatory class (MDD, Annex IX):	class IIa (Annex IX rule 10)
Conformity assessment procedure:	Annex V
GMDN	17887
UMDNS	14-036
Notified Body	DQS Medizinprodukte GmbH August Schanz Str. 21 D-60433 Frankfurt, Germany Registration number: 0297
EC Certificate	381008 MR5
EN ISO 13485 Certificate	381008 MP2016

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This declaration of conformity is valid until May 26, 2024.

Michael Burke		Lausanne	December 8, 2021
General Manager EMEA	Legally binding signature	Place	Date

Company Stamp:

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