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 IR Thermometer IRT6520, IRT6030, IRT6020 and IRT6515 series	IRT6520MNLA IRT6520WE IRT6520BWE IRT6520NOEE IRT6520KO IRT6520CN IRT6520AU IRT6520AP IRT6520LA IRT6520LAD1	IRT6030KO IRT6030CN IRT6030AU IRT6030AP IRT6020NOEE IRT6020MNLA IRT6515NOEE IRT6515MNLA

Standards Applied:

Standard Reference	Edition	Title
EN ISO 13485	2016	Medical devices — Quality management systems — Requirements for regulatory purposes
EN ISO 14971	2012	Medical devices — Application of risk management to medical devices.
EN 60601-1	2006/A1:2013	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
EN 60601-1-11	2015	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	Medical electrical equipment – part 1-2: General requirements for basic safety and essential performance – Collateral standard: electromagnetic compatibility – Requirements and tests.
EN 62304	2006/A1:2008	Medical device software – Software life-cycle processes.
EN 62366-1	2015	Medical devices — Application of usability engineering to medical devices.
EN 60601-1-6	2010/A1:2013	Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral Standard: Usability.
EN ISO 10993-1	2009/AC:2010	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
ISO 10993-10	2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
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/A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 80601-2-56	2017	Medical electrical equipment – Part 2-56: Particular requirements for basic safety and essential performance of clinical
ASTM E1965-98	2016	Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature
EN 12470-5	2000+A1:2009	Clinical thermometers - Part 2: Phase change type (dot matrix) thermometers
EN ISO 14155	2011/AC:2011	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, Place Chauderon 18, CH-1003 Lausanne, Switzerland

Additional information:

For Medical Device Directive 93/43/EC	
Regulatory class (MDD, Annex IX):	class IIa (Annex IX rule 10)
Conformity assessment procedure:	Annex V
GMDN	45617
UMDNS	17-887
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 June 26, 2023.

Mike Burke		Lausanne	05 March 2020
VP Sales and Marketing, General Manager EMEA	Legally binding signature	Place	Date

Company Stamp:

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