

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 EC Directive(s):

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

Name	Type or model
Braun IR Thermometer IRT6520, IRT6030, And IRT6020 series	IRT6520MNLA
	IRT6520WE
	IRT6520NOEE
	IRT6520KO
	IRT6520CN
	IRT6520AU
	IRT6520AP
	IRT6520LA
	IRT6520LAD1
	IRT6030KO
	IRT6030CN
	IRT6030AU
	IRT6030AP
	IRT6020NOEE
	IRT6020MNLA

Standards Applied:

Reference Number	Title	Date of Issue
EN 60601-1	Medical Electric Equipment- Part 1: General Requirements for Basic Safety and Essential Performance	2006
EN 60601-1-2	Medical Electrical Equipment – Part 1-2: General requirements for Basic Safety and Essential Performance- Collateral Standard: Electromagnetic Compatibility- Requirements and Tests	2007
EN 60601-1-6	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability	2010
EN 62366	Medical Devices – Application of usability engineering to medical devices	2008
EN 60601-1-11	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for	2010

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EN ISO 10993-1	medical electrical equipment and medical electrical systems used in the home healthcare environment. Biological Evaluation of Medical devices- Part 1: Evaluation and Testing	2009
ISO 80601-2-56	Medical electrical equipment – Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.	2009
EN 12470-5	Clinical Thermometers- Part 5 Performance of Infra-Red ear Thermometers (with maximum device)	2003
EN 62304	Medical Device Software-Software Life Cycle Processes	2006
EN ISO 14971	Medical devices- Application of risk management to medical devices.	2012
EN 980	Symbols for Use in the Labeling of Medical Devices	2008
EN 1041	Information supplied by the manufacturer with Medical Devices	2008
ASTM E1965-98	Standard Specification for infrared Thermometers for Intermittent Determination of Patient Temperature	2003

Conformity assessment procedure:

Device Classification	Annex	GMDN	UMDNS
Ila (Annex IX rule 10)	V	17887	14-036

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

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The declaration of conformity is valid until 2020-06-26.

Roelof Zeijpveld



Lausanne

May 17, 2017

Senior Vice-President, General
Manager EMEA

Legally binding signature

Place

Date

Company Stamp:

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