

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 ThermoScan 3 IR Thermometer IRT3030

IRT3030
IRT3030WE
IRT3030EE
IRT3030LA
IRT3030LAD1
IRT3030AR

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	2013	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
EN 60601-1-2:2007/AC:2010	2010	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	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	2012	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/AC:2008	2008	Medical device software – Software life-cycle processes.

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EN 980	2008	Symbols for use in labeling of medical devices.
EN 1041	2008	Information supplied by the manufacturer of medical devices.
EN 62366	2008	Medical devices — Application of usability engineering to medical devices.

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.

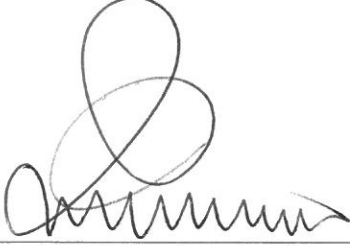
Notified body: DQS Medizinprodukte GmbH, August Schanz Str.21, D-60433, Frankfurt, Germany (registration number: 0297)

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

Roelof Zeijpveld		Lausanne	14 March 2016
General Manager	Legally binding signature	Place	Date

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