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
IIa (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)

Authorized Representative in Turkey: Sistem Çözüm Ortaklığı Satış Dağıtım Tic. Ltd. Şti.

Address: Ortaklar Cad. Bahçeler Sok.
18 İş Merkezi K:4 D:7 Mecidiyeköy
34394 Istanbul

Tel: +90 212 216 2950

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

Roelof Zeijpveld — Lausanne — 14 March 2016

General Manager | Legally binding signature | Place | Date

Company Stamp:

Kaz Europe Sàrl
(formerly Kaz Europe SA)
Place Chauderon 18
CH-1003 Lausanne
T. +41 21 644 01 10
F. +41 21 644 01 11