

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

DIRECTIVE 2007/47/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market

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 (recast)

Name	Type or model
Braun IR Thermometer IRT6520, IRT6030, And IRT6020 series	IRT6520MNLA IRT6520WE IRT6520BWE 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	2015
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

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EN 60601-1-11	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.	2010
EN ISO 10993-1	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

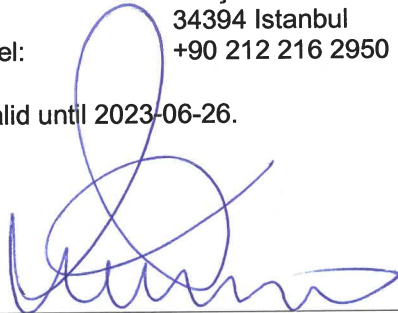
Notified body for CE marking under 93/42/EEC: DQS Medizinprodukte GmbH, August Schanz Str.21, D-60433, Frankfurt, Germany (registration number: 0297)

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 İstanbul
Tel: +90 212 216 2950

The declaration of conformity is valid until 2023-06-26.

Roelof Zeijpveld



Lausanne

2019-07-17

Senior Vice-President, General
Manager EMEA

Legally binding signature

Place

Date

Company Stamp:

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