# 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<br>IRT6520WE<br>IRT6520BWE<br>IRT6520NOEE<br>IRT6520KO<br>IRT6520CN<br>IRT6520AU<br>IRT6520AP<br>IRT6520LA<br>IRT6520LAD1<br><br>IRT6030KO<br>IRT6030CN<br>IRT6030AU<br>IRT6030AP<br><br>IRT6020NOEE<br>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 |

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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 |
|---|---|---|---|
| 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 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.

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

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|---|---|---|---|
| Roelof Zeijpveld<br>p.o. Alexia Fernández<br>Senior Vice-President, General Manager EMEA | Legally binding signature | Lausanne<br>Place | 2018-11-19<br>Date |

Company Stamp: