EC Declaration of Conformity

Conformity assessment procedure:

Device Classification	Annex	UMDNS
IIa (Annex IX rule 10)	V	14-032

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 İstanbul
Turkey

Tel: +90 212 216 2950

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

Roelof Zeijpveld — General Manager — Legally binding signature — Lausanne — Place — 15 May 2017 — 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

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 Digital Thermometer PRT1000 series	PRT1000CE PRT1000EE

Standards Applied:

Reference Number	Title	Date of issue
EN 60601-1	Medical electrical equipment - Part 1: General requirements for 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 60601-1-11	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 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 62304	Medical device software - Software life-cycle processes	2006
EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing	2003
EN 12470-3	Clinical thermometers - Part 3: Performance of compact electrical thermometers (non-predictive and predictive) with maximum device	2009
EN ISO 14971	Medical devices - Application of risk management to medical devices	2012
EN 980	Graphical symbols for use in the labelling of medical devices	2008
EN 1041	Information supplied by the manufacturer with medical devices	2008