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 below Directive(s):

- **MDD - Council Directive 93/42/EEC of 14 June 1993 concerning medical devices**
- **RoHS - 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**

Name	**Type or model**
Braun Age precision Digital Thermometer PRT2000 series	PRT2000EU

Standards Applied:

Standard Reference	Edition	Title
EN 60601-1	2006 / A1:2013	Medical electrical equipment - Part 1: General requirements for safety and essential performance.
EN 60601-1-2	2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-11	2010	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
EN 60601-1-6	2010	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62366	2008	Medical devices - Application of usability engineering to medical devices
EN 62304	2006	Medical device software - Software life-cycle processes
EN ISO 10993-1	2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing
EN 12470-3	2009	Clinical thermometers - Part 3: Performance of compact electrical thermometers (non-predictive and predictive) with maximum device
ISO 80601-2-56	2009	Medical electrical equipment -- Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
EN ISO 14971	2012	Medical devices - Application of risk management to medical devices
EN 980	2008	Graphical symbols for use in the labelling of medical devices
EN 1041	2008	Information supplied by the manufacturer with medical devices

The Technical Documentation is the responsibility of: Kaz Europe Sàrl, Place Chauderon 18, CH-1003 Lausanne, Switzerland

EC Declaration of Conformity

Additional information:

For Medical Device Directive 93/43/EC	
Regulatory class (MDD, Annex IX):	class IIa (Annex IX rule 10)
Conformity assessment procedure:	Annex V
GMDN	37340
UMDNS	14-032
Notified Body	DQS Medizinprodukte GmbH August Schanz Str. 21 D-60433 Frankfurt, Germany Registration number: 0297
EC Certificate	381008 MR5
EN ISO 13485 Certificate	381008 MP2016

Authorized Representative in Europe: Obelis, S.A.
Address: Bd. Général Wahis, 53
1030 Brussels, Belgium

Authorized Representative in Turkey: Sistem Çözüm Ortaklığı Satış Dağıtım Tic. Ltd. Şti.
Address: Ortaklar Cad. Bahçeler Sok.
18 İş Merkezi K:3 D:5 Mecidiyeköy
34394 İstanbul, Turkey
Tel: +90 212 216 2950

This declaration of conformity is valid until May 26, 2024.

Michael Burke p.o. Alain Feuillaz		Lausanne	June 30, 2021
General Manager EMEA	Legally binding signature	Place	Date

Company Stamp:

Helen of Troy
Kaz Europe Sàrl
Place Chauderon 18
1003 Lausanne
Switzerland
Tel. +41 21 644 01 10
Fax +41 21 644 01 11