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 TempleSwipe thermometer BST200	BST200WE BST200EE

Standards Applied:

Standard Reference	Edition	Title
EN ISO 13485	2016	Medical devices — Quality management systems — Requirements for regulatory purposes
EN ISO 14971	2012	Medical devices — Application of risk management to medical devices.
EN 60601-1	2006/A12:2014	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
EN 60601-1-11	2015	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 60601-1-2	2015	Medical electrical equipment – part 1-2: General requirements for basic safety and essential performance – Collateral standard: electromagnetic compatibility – Requirements and tests.
EN 62304	2006/A1:2015	Medical device software – Software life-cycle processes.
EN 62366-1	2015	Medical devices — Application of usability engineering to medical devices.
EN 60601-1-6	2010/A1:2013	Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral Standard: Usability.
EN ISO 10993-1	2009	Biological evaluation of medical devices — Part 1: Evaluation and testing.
EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10	2013	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
EN ISO 15223-1	2016	Symbols to be used with medical device labels, labeling, and information to be supplied -- Part 1 – General requirements
EN 1041	2008/A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 80601-2-56	2017	Medical electrical equipment – Part 2-56: Particular requirements for basic safety and essential performance of clinical
ASTM E1965-98	2016	Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature
EN ISO 14155	2011/AC:2011	Clinical investigation of medical devices for human subjects - Good clinical practice

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	17888
UMDNS	14036
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:
Address:

Obelis, S.A.
Bd. Général Wahis, 53
1030 Brussels, Belgium

Authorized Representative in Turkey:
Address:

Sistem Çözüm Ortaklığı Satış Dağıtım Tic. Ltd. Şti.
Ortaklar Cad. Bahçeler Sok.
18 İş Merkezi K:3 D:5 Mecidiyeköy
34394 İstanbul, Turkey

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

Michael Burke		Lausanne	May 20, 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