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 No touch + touch thermometer BNT400	BNT400WE BNT400EE BNT400BWE BNT400 BNT400WEGP (BNT400WE + a Toy book)

Note: BNT400WEGP is sold with a learning book toy into the packaging. The toy is covered by his own EC Declaration of Conformity under the Toy Safety Directive with Horst Lechner 3D-Promotion e.U. Füllenberggasse 156a, 2393 Sittendorf, Austria as manufacturer. It is imported/distributed by KAZ Europe Sàrl

Standards Applied:

Standard Reference	Edition	Title
EN 60601-1	2006 + A1:2013	Medical Electric Equipment- Part 1: General Requirements for Basic 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 60601-1-6	2010	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
EN 62366	2008	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 ISO 10993-1	2009	Biological Evaluation of Medical devices- Part 1: Evaluation and Testing
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 62304	2006	Medical Device Software-Software Life Cycle Processes
EN ISO 14971	2019	Medical devices- Application of risk management to medical devices.
EN 15223-1	2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN 1041	2008	Information supplied by the manufacturer with Medical Devices

EC Declaration of Conformity

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

Additional Information:

For Medical Device Directive 93/42/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: 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		Lausanne	May 03, 2022
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