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 Digital Thermometer PRT1000 series	PRT1000CE PRT1000EE

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.
IEC 60601-1 EN 60601-1	2005 + A1:2012 2006 + A12:2013	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
IEC 60601-1-11 EN 60601-1-11	2015 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 60601-1-6	2010	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62366-1	2015	Medical devices - Application of usability engineering to medical devices
EN 62304	2006 + A1:2013	Medical device software - Software life-cycle processes
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
EN 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.
ISO 80601-2-56 EN ISO 80601-2-56	2017 + A1:2018 2017 + A1:2020	Medical electrical equipment – Part 2-56: Particular requirements for basic safety and essential performance of clinical
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

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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

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

Michael Burke		Lausanne	20 May 2021
General Manager EMEA	Legally binding signature	Place	Date

Company Stamp:

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