

EC Declaration of Conformity

We, **Kaz Europe Sàrl**, Place Chauderon 18, 1003 Lausanne, Switzerland declares 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 ISO 13485	2016	Medical devices — Quality management systems — Requirements for regulatory purposes
EN ISO 14971	2019	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 + A1:2008	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 + AC:2010	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	2010	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 8061-2-56	2017 + A1:2018	Medical electrical equipment – Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
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 93/42/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 -See Annex: Manufacturer's Declaration signed on 06 May 2024
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
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Tel:

This declaration of conformity is valid until December 31, 2028.

Michael Burke
General Manager
EMEA

Legally
binding
signature

Maud Giorgi
PRRC, QMS & Regulatory
Affairs Manager EMEA

Legally
binding
signature

Bussigny

May 13,
2024

Company
Stamp:

Place

Date



Kaz Europe Sàrl
Route de la Chaux 4
1030 Bussigny sur Lausanne
Switzerland
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23 January 2025

Annex Change history: DOC MD 0028 - product PRT2000

We, Kaz Europe Sarl, confirmed that the last version of this Declaration of conformity before May 26, 2021 was the 06 (signed and dated on 20 May 2021).

After this revision, please see below the history of the nexts with description:

Revision	Signature date	Change description
06	20 May 2021	Last version before May 26, 2021
07	30 June 2021	Non-Significant changes: • Removal of variants PRT2000AR and PRT2000MX
08	08 December 2021	Non-Significant changes: • Change of EN ISO 14971 edition, from 2012 to 2019 • Change of EN ISO 15223-1 edition, from 2008 to 2016 • Correction of typo in Directive 93/42/EC (page 2)
09	14 February 2022	Non-Significant changes: • Replace EN 60601-1 edition 2006+A1:2013 with IEC 60601-1 edition 2006 + A1:2012 • Added A1:2023 for the edition of EN 60601-1-6 • Added AC:2008 for the edition of EN 62304 • Removal of EN 12470-3 edition 2009 • Added ISO 10993-5 edition 2009 • Added ISO 10993-10 edition 2010 • Replaced ISO 80601-2-56 edition 2009 with EN ISO 80601-2-56 edition 2017 + A1:2018
10	11 March 2022	Non-Significant changes: • Added EN ISO 13485 edition 2016 • Replace edition A1:2012 of EN 60601-1 with A1:2014 • Replace EN 62366 edition 2008 with EN 62366-1 edition 2015 • Added EN for the standard ISO 10993-5 • Added A1:2013 for the edition of the EN1041 • Added EN ISO 14155 edition 2011 + AC:2011
11	13 May 2024	Non-Significant changes: • Added PRRC signature • In the CE Certificate data: added the manufacturer's declaration signed on 06 May 2024 • Change of validity of the declaration, from May 26, 2024 to December 31, 2028 (as per MDR, article 120 transition).

Maud Giorgi

Associate QMS and Regulatory Director

Signed by Maud Giorgi



Maud Giorgi

I approve this document
January 28, 2025 | 1:56:33 PM CET

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Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*¹
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Kaz Europe Sàrl
Manufacturer address and contact details	Q-center, Route de la Chaux 4 1030 Bussigny, Switzerland
EU Single Registration Number (SRN)	CH-MF-000029980
Swiss Single Registration Number (Swiss SRN)	CHRN-MF-20000627

European Authorised Representative name	Obelis, S.A.
European Authorised Representative address	Bd. Général Wahis, 53 1030 Brussels, Belgium
Single Registration Number (SRN)	BE-AR-000000106

Notified body name	DQS Medizinprodukte GmbH See attached schedule for more details
Notified body number	0297 See attached schedule for more details
Directive Certificate number(s) to which this confirmation is made	93/42/EEC See attached schedule for more details
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	May 26, 2024 See attached schedule for more details
End date of extended validity/transition period	Dec 31, 2028 See attached schedule for more details

¹ The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*²
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service, namely by fulfilling the following conditions:

➤ **Directive Certificate** as listed above or in the attached schedule

- Directive Certificate covering the listed device(s) was issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards.

☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

- ☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ **Upclassified devices:** Not applicable

➤ **Quality Management System (QMS)**

Choose one applicable statement:

- ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- ☒ A QMS in accordance with Article 10(9) MDR is in place.
- ☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➤ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

² The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

Signed for and on behalf of the manufacturer:

KAZ Europe Sàrl

Michael Burke
General Manager EMEA

Signature



Date
Place

May 06, 2024
Bussigny, Switzerland

Maud Giorgi
QMS & RA Manager, EMEA
Contact details:
Quality_EMEA@helenoftroy.com
Signature



Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s) ³ (e.g., device name, family/group name, device model or catalogue number)	Directive Certificate number to which this confirmation is made	Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the MDR application was lodged/contract signed	End date of extended validity / transition period	Substitute Device(s)
BST200	381008 MR5	May 26, 2024	DQS Medizinprodukte GmbH, 0297	DQS Medizinprodukte GmbH, 0297	Dec 31, 2028	N/A
BNT300	381008 MR5	May 26, 2024	DQS Medizinprodukte GmbH, 0297	DQS Medizinprodukte GmbH, 0297	Dec 31, 2028	N/A
BNT400	381008 MR5	May 26, 2024	DQS Medizinprodukte GmbH, 0297	DQS Medizinprodukte GmbH, 0297	Dec 31, 2028	N/A
IRT3030	381008 MR5	May 26, 2024	DQS Medizinprodukte GmbH, 0297	DQS Medizinprodukte GmbH, 0297	Dec 31, 2028	N/A
IRT6030	381008 MR5	May 26, 2024	DQS Medizinprodukte GmbH, 0297	DQS Medizinprodukte GmbH, 0297	Dec 31, 2028	N/A
IRT6515	381008 MR5	May 26, 2024	DQS Medizinprodukte GmbH, 0297	DQS Medizinprodukte GmbH, 0297	Dec 31, 2028	N/A
IRT6520	381008 MR5	May 26, 2024	DQS Medizinprodukte GmbH, 0297	DQS Medizinprodukte GmbH, 0297	Dec 31, 2028	N/A
IRT6525	381008 MR5	May 26, 2024	DQS Medizinprodukte GmbH, 0297	DQS Medizinprodukte GmbH, 0297	Dec 31, 2028	N/A
PRT1000	381008 MR5	May 26, 2024	DQS Medizinprodukte GmbH, 0297	DQS Medizinprodukte GmbH, 0297	Dec 31, 2028	N/A
PRT2000	381008 MR5	May 26, 2024	DQS Medizinprodukte GmbH, 0297	DQS Medizinprodukte GmbH, 0297	Dec 31, 2028	N/A
LF40, LF20	381008 MR5	May 26, 2024	DQS Medizinprodukte GmbH, 0297	DQS Medizinprodukte GmbH, 0297	Dec 31, 2028	N/A
BUA5000	381008 MR5	May 26, 2024	DQS Medizinprodukte GmbH, 0297	DQS Medizinprodukte GmbH, 0297	Dec 31, 2028	N/A
BUA6150	381008 MR5	May 26, 2024	DQS Medizinprodukte GmbH, 0297	DQS Medizinprodukte GmbH, 0297	Dec 31, 2028	N/A
BUA6350	381008 MR5	May 26, 2024	DQS Medizinprodukte GmbH, 0297	DQS Medizinprodukte GmbH, 0297	Dec 31, 2028	N/A
BNA100	381008 MR5	May 26, 2024	DQS Medizinprodukte GmbH, 0297	DQS Medizinprodukte GmbH, 0297	Dec 31, 2028	N/A

³ for devices with MDD certificate the identification should be as in the certificate