



EU Quality Management Certificate



This is to certify that the company

Kaz Europe Sàrl

Q-Center

Route de la Chaux 4
1030 Bussigny
Switzerland

SRN: CH-MF-000029980

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745 **Conformity Assessment based on a Quality Management System and on Assessment of** **Technical Documentation**

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3. Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	381008 MDR2017Q
Certificate ID	1000183824
Effective date	2024-07-30
Expiry date	2029-07-29
Frankfurt am Main,	2024-07-30



DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)



Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745
of the Council concerning medical devices with the Identification Number 0297.
The validity of the certification can only be verified by the QR-code.



Annex to EU Quality Management Certificate
SRN of Manufacturer: CH-MF-000029980
Certificate ID: 1000183824

Authorised Representative of the company:

Obelis, S.A.

Bd. Général Wahis, 53,
1030 Brussels
Belgium

SRN: BE-AR-000000106

Device categories and variants covered by this certificate:

Device category: **MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters**
Product name: Braun High Speed thermometer PRT1000
Risk classification: IIa
Basic-UDI-DI: 76307593PR1000J9
Intended purpose: The Braun thermometer is intended to be used by home users for intermittent measurement of the body temperature of patients at the following measuring sites (oral, rectal and underarm). For home usage only.

Device category: **MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters**
Product name: Braun Age Precision digital thermometer PRT2000
Risk classification: IIa
Basic-UDI-DI: 76307593PR2000JG
Intended purpose: The Braun thermometer is intended to be used by home users for intermittent measurement of the body temperature of patients at the following measuring sites (oral, rectal and underarm). For home usage only.

Device category: **MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters**
Product name: Braun ThermoScan 3 IRT3030
Risk classification: IIa
Basic-UDI-DI: 76307593IR3030G5
Intended purpose: The Braun ThermoScan® Ear thermometer is intended to be used by home users for intermittent measurement of the body temperature of patients having ages ranging from normal weight (full term) new-born to geriatric adult. The thermometer is reusable.



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Device category: **MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters**

Product name: Braun ThermoScan 5 IRT6020
Braun ThermoScan 5 IRT6030
Braun ThermoScan 6 IRT6515
Braun ThermoScan 7 IRT6520
Braun ThermoScan 7+ IRT6525
Braun ThermoScan 7+ connect IRT6575

Risk classification: IIa
Basic-UDI-DI: 76307593IR6000GH

Intended purpose: The Braun ThermoScan® Ear thermometer is intended to be used by home users for intermittent measurement of the body temperature of patients having ages ranging from normal weight (full term) new-born to geriatric adult. The thermometer is reusable.

Device category: **MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters**

Product name: Braun TempleSwipe thermometer BST200

Risk classification: IIa
Basic-UDI-DI: 76307593BST200LN

Intended purpose: This Braun thermometer is an handheld, battery-powered, infrared thermometer intended for the intermittent measurement of human body temperature in a home-use environment on people of all ages, except pre-term and small-for-gestational-age babies.

Device category: **MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters**

Product name: Braun ExactFit 3 BUA6150
Braun ExactFit 5 Connect BUA6350

Risk classification: IIa
Basic-UDI-DI: 76307593BP6000CY

Intended purpose: This device is intended to be used by adults (+18 years old) to measure people's blood pressure that includes systolic, diastolic and heartbeat pulse rate. This device is to be used for intermittent measurements only. For home usage only.

Device category: **MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters**

Product name: Braun ExactFit 1 BUA5000

Risk classification: IIa
Basic-UDI-DI: 76307593BU5000EG

Intended purpose: This device is intended to be used by adults (+18 years old) to measure people's blood pressure that includes systolic, diastolic and heartbeat pulse rate. This device is to be used for intermittent measurements only. For home usage only.



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Device category: **MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters**
Product name: Braun ExactFit 1E BUA4000
Braun ExactFit 2 BUA4050
Risk classification: IIa
Basic-UDI-DI: 76307593BP4000CJ
Intended purpose: This device is intended to be used by adults (+18 years old) to measure people's blood pressure that includes systolic, diastolic and heartbeat pulse rate. This device is to be used for intermittent measurements only. For home usage only.

Device category: **MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters**
Product name: Braun Sensian 5 Non-contact thermometer BNT300
Braun Sensian 7 Non-contact thermometer BNT400
Risk classification: IIa
Basic-UDI-DI: 76307593BN400GQ
Intended purpose: This No touch + touch thermometer is an handheld, battery-powered, infrared thermometer intended for the intermittent measurement of human body temperature in a home-use environment on people of all ages, except pre-term and small-for-gestational-age babies, using the center of the forehead as the measurement site.

Device category: **MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters**
Product name: Braun Sensian 3 Non-contact thermometer BNT050
Risk classification: IIa
Basic-UDI-DI: 76307593BNT050K4
Intended purpose: This non-contact forehead thermometer is an handheld, battery-powered, infrared thermometer intended for the intermittent measurement of human body temperature in a home-use environment on people of all ages, except pre-term and small-for-gestational-age babies, using the center of the forehead as the measurement site.

Device category: **MDA 0315 - Software**
Product name: Braun Family Care App BT900
Risk classification: IIa
Basic-UDI-DI: 76307593BFCAPPKH
Intended purpose: The Braun Family Care mobile application is intended to be used by adults on subjects of all ages in the home-use environment for organizing, tracking, trending, and controlled sharing of reported temperature information, in combination with related supplementary information including age, notes, symptoms, and medication usage. In addition, the app acts as a source of limited triage and home care advice to reference information that is validated and routinely used in clinical practice, without altering or changing the previous temperature reading/s from connected thermometers.



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Examinations and tests performed:

381008_A211308MED_01 dated 06.07.2024

381008_A211308MED_02 Braun Thermoscan 7+ Connect Ear Thermometer dated 02.01.2024

381008_A211308MED_03 BT900 Braun Family Care App dated 17.07.2024

381008_A211308MED_04 BUA4000 ExactFit™ 1E and BUA4050 ExactFit™ 2 dated 20.07.2024

Further conditions for or limitations to the validity of the certificate:

n/a

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
n/a	n/a	n/a	n/a