EC-CERTIFICATE

(Production quality assurance)

This is to certify that the company

Kaz Europe Sàrl

Place Chauderon 18
1003 Lausanne
Switzerland

has implemented and maintains a quality assurance system which applies to the manufacture and final controls of the products.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex V of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Devices for vital parameter monitoring according to annex

The manufacturer is subject to surveillance according to Annex V, Section 4. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	381008 MR5
Certificate unique ID	170774273
Effective date	2021-04-21
Expiry date	2024-05-26
Frankfurt am Main	2021-04-21

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

411.21 Version 1.0

Annex to certificate
Certificate registration No.: 381008 MR5
Certificate unique ID: 170774273
Effective date: 2021-04-21

Kaz Europe Sàrl

Place Chauderon 18
1003 Lausanne
Switzerland

Device family	Device	Class
Devices for vital-parameter monitoring	Vicks/Wick IR Thermometer (Forehead) VFH100 and WFH100 series, BST200	IIa
	Vicks No Touch Thermometer VNT200	IIa
	Braun Blood Pressure Monitor (wrist), BBP2000 and BBP2200	IIa
	Braun Blood Pressure Monitor (wrist) Type BPW4500	IIa
	Braun Blood Pressure Monitor (upper arm) BP6000 series (BP6000, BP6100 and BP6200)	IIa
	Braun ExactFit™ 3 / ExactFit™ 5 Blood Pressure Monitor BP6000 series (BUA6150WE, BUA6150CEME, BUA6350, BP6200PHEMEAV1)	IIa
	Braun No Touch + Forehead Thermometer (also named as Braun Touchless + Forehead Thermometer) NTF3000 series NTF 3000 NTF3000WE NTF3000EE NTF3000AP NTF3000KO NTF3000AU NTF3000CN BNT400 BNT300	IIa
	Braun IR Thermometer Type 3000, IRT3030	IIa
	Braun Digital Thermometer Type 1000, PRT1000, PRT2000	IIa
	Protection Cap for IRT thermometer Type LF20, PC20, LF40 (double pack)	IIa
	Braun IR Thermometer Type 6000, IRT6020, IRT6520, IRT6030, IRT6515, IRT6525	IIa
Devices for vital-parameter monitoring	Braun Blood Pressure Monitor (upper arm) BUA5000 BUA5000EU BUA5000LA BUA5000LAD1 BUA7200	IIa
	Braun® BNA100 Nasal Aspirator	IIa

This annex is only valid in connection with the above-mentioned certificate.

DQS Medizinprodukte GmbH | August-Schanz-Str. 21 | 60433 Frankfurt am Main

Kaz Europe Sàrl

Q-Center

Route de la Chaux 4
1030 Bussigny
Switzerland

Date: 2024-05-24

Notified Body Confirmation Letter
Reference: 1000179480

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DQS Medizinprodukte GmbH, a Notified Body designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0297 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Kaz Europe Sàrl

Route de la Chaux 4
1030 Bussigny
Switzerland

SRN: CH-MF-000029980

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables listed below: Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which DQS Medizinprodukte GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but DQS Medizinprodukte GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.
In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices. The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices

- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Viviana Indraccolo
Regulatory Affairs Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Braun TempleSwipe thermometer (ref: BST200) 76307593BST200LN	Class IIa	N/A	381008 MR5 170773847 (NB 0297)
Braun Sensian 5 Noncontact thermometer (ref: BNT300) 76307593BN400GQ	Class IIa	N/A	381008 MR5 170773847 (NB 0297)
Braun Sensian 7 Noncontact thermometer (ref: BNT400) 76307593BN400GQ	Class IIa	N/A	381008 MR5 170773847 (NB 0297)
Braun ThermoScan 3 (ref: IRT3030) 76307593IR3030G5	Class IIa	N/A	381008 MR5 170773847 (NB 0297)
Braun ThermoScan 5 (ref: IRT6030) 76307593IR6000GH	Class IIa	N/A	381008 MR5 170773847 (NB 0297)
Braun ThermoScan 6 (ref: IRT6515) 76307593IR6000GH	Class IIa	N/A	381008 MR5 170773847 (NB 0297)
Braun ThermoScan 7 (ref: IRT6520) 76307593IR6000GH	Class IIa	N/A	381008 MR5 170773847 (NB 0297)
Braun ThermoScan 7+ (ref: IRT6525) 76307593IR6000GH	Class IIa	N/A	381008 MR5 170773847 (NB 0297)
Braun High Speed thermometer (ref: PRT1000) 76307593PR1000J9	Class IIa	N/A	381008 MR5 170773847 (NB 0297)
Braun Age Precision digital thermometer (ref: PRT2000) 76307593PR2000JG	Class IIa	N/A	381008 MR5 170773847 (NB 0297)

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Braun ThermoScan Hygiene cap (ref: LF40/LF20) 76307593LF4020DC	Class IIa	N/A	381008 MR5 170773847 (NB 0297)
Braun ExactFit 1 (ref: BUA5000) 76307593BU5000EG	Class IIa	N/A	381008 MR5 170773847 (NB 0297)
Braun ExactFit 3 (ref: BUA6150) 76307593BP6000CY	Class IIa	N/A	381008 MR5 170773847 (NB 0297)
Braun ExactFit 5 connect (ref: BUA6350) 76307593BP6000CY	Class IIa	N/A	381008 MR5 170773847 (NB 0297)
Braun Nasal aspirator 1 (ref: BNA100) 76307593BNT100JS	Class IIa	N/A	381008 MR5 170773847 (NB 0297)
Braun ThermoScan 5 IRT6020 76307593IR6000GH	Class IIa	N/A	381008 MR5 170773847 (NB 0297)
Braun ExactFit 5 BP6200PHEMEAV1 76307593BP6000CY	Class IIa	N/A	381008 MR5 170773847 (NB 0297)
Braun iCheck 7 BPW4500 76307593BP4500DB	Class IIa	N/A	381008 MR5 170773847 (NB 0297)

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

17Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-05-17	1000178686	Initial issue
22024-05-23	1000179480	Registration issues in system – New Internal Reference issued