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

H.P. Braem AG

Industriestrasse 4

9552 Bronschhofen

Schweiz

12/8/2023

Notified Body Confirmation Letter

Reference: Certificate registration no.: 060431

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 device

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:

H.P. Braem AG

Industriestrasse 4

9552 Bronschhofen

Switzerland

SRN: CH-MF-000016254

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR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,

Schiwa Karimi

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
12300 28 kHz Phaco handpiece 764014986PA01PHACOZF	Class IIa - Active therapeutic device intended to administer or exchange energy	N/A	Cert-ID: 170741769 (NB 0297)
12350 28 kHz Phaco handpiece G 764014986PA01PHACOZF	Class IIa - Active therapeutic device intended to administer or exchange energy	N/A	Cert-ID: 170741769 (NB 0297)
12306 Phaco Accessoires Set 19G 30° sterile 764014986PA01PHACOZF	Class IIa - Surgically invasive device intended for transient use	N/A	Cert-ID: 170741769 (NB 0297)
12307 Phaco Accessoires Set sterile 19G 30° bent 764014986PA01PHACOZF	Class IIa - Surgically invasive device intended for transient use	N/A	Cert-ID: 170741769 (NB 0297)
12308 Phaco Accessoires Set 20G 30° sterile 764014986PA01PHACOZF	Class IIa - Surgically invasive device intended for transient use	N/A	Cert-ID: 170741769 (NB 0297)
12309 Phaco Accessories Set sterile bent 20G 30° 764014986PA01PHACOZF	Class IIa - Surgically invasive device intended for transient use	N/A	Cert-ID: 170741769 (NB 0297)
12311 Phaco Accessoires Set 22G 30° sterile 764014986PA01PHACOZF	Class IIa - Surgically invasive device intended for transient use	N/A	Cert-ID: 170741769 (NB 0297)
12312 Phaco Accessories Set sterile bent 22G 30° 764014986PA01PHACOZF	Class IIa - Surgically invasive device intended for transient use	N/A	Cert-ID: 170741769 (NB 0297)
12406 Phaco Accessories Set 19G 30° 764014986PA01PHACOZF	Class IIa - Surgically invasive device intended for transient use	N/A	Cert-ID: 170741769 (NB 0297)
12407 Phaco Accessories Set bent 19G 30° 764014986PA01PHACOZF	Class IIa - Surgically invasive device intended for transient use	N/A	Cert-ID: 170741769 (NB 0297)
12408 Phaco Accessories Set 20G 30° 764014986PA01PHACOZF	Class IIa - Surgically invasive device intended for transient use	N/A	Cert-ID: 170741769 (NB 0297)
12409 Phaco Accessories Set bent 20G 30° 764014986PA01PHACOZF	Class IIa - Surgically invasive device intended for transient use	N/A	Cert-ID: 170741769 (NB 0297)
12411 Phaco Accessories Set 22G 30° 764014986PA01PHACOZF	Class IIa - Surgically invasive device intended for transient use	N/A	Cert-ID: 170741769 (NB 0297)
12412 Phaco Accessories Set bent 22G 30° 764014986PA01PHACOZF	Class IIa - Surgically invasive device intended for transient use	N/A	Cert-ID: 170741769 (NB 0297)
10302 Mega Tip / 19G / 30° 764014986PA01PHACOZF	Class IIa - Surgically invasive device intended for transient use	N/A	Cert-ID: 170741769 (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
12318 Hypersonic Phaco Tip 19G 30° bent 764014986PA01PHACOZF	Class IIa - Surgically invasive device intended for transient use	N/A	Cert-ID: 170741769 (NB 0297)
12319 Hypersonic Phaco Tip 19G 30° 764014986PA01PHACOZF	Class IIa - Surgically invasive device intended for transient use	N/A	Cert-ID: 170741769 (NB 0297)
12320 Hypersonic Tip 20G 30° 764014986PA01PHACOZF	Class IIa - Surgically invasive device intended for transient use	N/A	Cert-ID: 170741769 (NB 0297)
12321 Hypersonic Phaco Tip 20G 30° bent 764014986PA01PHACOZF	Class IIa - Surgically invasive device intended for transient use	N/A	Cert-ID: 170741769 (NB 0297)
12322 Hypersonic Tip 22G 30° 764014986PA01PHACOZF	Class IIa - Surgically invasive device intended for transient use	N/A	Cert-ID: 170741769 (NB 0297)
12323 Titan Tip Hi Vac 20G 764014986PA01PHACOZF	Class IIa - Surgically invasive device intended for transient use	N/A	Cert-ID: 170741769 (NB 0297)
12324 Hypersonic Phaco Tip 22G 30° bent 764014986PA01PHACOZF	Class IIa - Surgically invasive device intended for transient use	N/A	Cert-ID: 170741769 (NB 0297)
12333 Fragmatome Phaco Tip 23G 30mm 0°-30° 764014986PA01PHACOZF	Class IIa - Surgically invasive device intended for transient use	N/A	Cert-ID: 170741769 (NB 0297)
10215 Silicon Sleeve 19G transparent Set à 2 pieces 764014986PA01PHACOZF	Class IIa - Surgically invasive device intended for transient use	N/A	Cert-ID: 170741769 (NB 0297)
10216 Silicon Sleeve 20G transparent Set à 2 pieces 764014986PA01PHACOZF	Class IIa - Surgically invasive device intended for transient use	N/A	Cert-ID: 170741769 (NB 0297)
10217 Silicon Sleeve 22G transparent Set à 2 pieces 764014986PA01PHACOZF	Class IIa - Surgically invasive device intended for transient use	N/A	Cert-ID: 170741769 (NB 0297)
10255 Silicon Sleeve 19G transparent Set à 100 pieces 764014986PA01PHACOZF	Class IIa - Surgically invasive device intended for transient use	N/A	Cert-ID: 170741769 (NB 0297)
10256 Silicon Sleeve 20G transparent Set à 100 pieces 764014986PA01PHACOZF	Class IIa - Surgically invasive device intended for transient use	N/A	Cert-ID: 170741769 (NB 0297)
10257 Silicon Sleeve 22G transparent Set à 100 pieces 764014986PA01PHACOZF	Class IIa - Surgically invasive device intended for transient use	N/A	Cert-ID: 170741769 (NB 0297)
22060 Cataract probe straight Ø 2 mm 764014986PA02CRYONR	Class IIb - Active therapeutic devices intended to administer or exchange energy	N/A	Cert-ID: 170741769 (NB 0297)
22064 Cataract probe bent Ø 2 mm 764014986PA02CRYONR	Class IIb - Active therapeutic devices intended to administer or exchange energy	N/A	Cert-ID: 170741769 (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
22068 Retina probe for infants Ø 1.6 mm / 60° 764014986PA02CRYONR	Class IIb - Active therapeutic devices intended to administer or exchange energy	N/A	Cert-ID: 170741769 (NB 0297)
22072 Retina probe ball Ø 2.5 mm / 60° 764014986PA02CRYONR	Class IIb - Active therapeutic devices intended to administer or exchange energy	N/A	Cert-ID: 170741769 (NB 0297)
22074 Retina probe ball, bulb Ø 2.5 mm / 60° 764014986PA02CRYONR	Class IIb - Active therapeutic devices intended to administer or exchange energy	N/A	Cert-ID: 170741769 (NB 0297)
22076 Retina probe ball, long Ø 2.5 mm / 60° 764014986PA02CRYONR	Class IIb - Active therapeutic devices intended to administer or exchange energy	N/A	Cert-ID: 170741769 (NB 0297)
22080 Retina probe ball Ø 3 mm / 90° 764014986PA02CRYONR	Class IIb - Active therapeutic devices intended to administer or exchange energy	N/A	Cert-ID: 170741769 (NB 0297)
22084 Glaucoma probe Ø 3 mm / 70° 764014986PA02CRYONR	Class IIb - Active therapeutic devices intended to administer or exchange energy	N/A	Cert-ID: 170741769 (NB 0297)
22088 Retina probe spatula bent, 4 mm / 60° 764014986PA02CRYONR	Class IIb - Active therapeutic devices intended to administer or exchange energy	N/A	Cert-ID: 170741769 (NB 0297)
22090 Retina probe spatula straight, 4 mm 764014986PA02CRYONR	Class IIb - Active therapeutic devices intended to administer or exchange energy	N/A	Cert-ID: 170741769 (NB 0297)
22092 Trichiasis probe 4 mm x 10 mm 764014986PA02CRYONR	Class IIb - Active therapeutic devices intended to administer or exchange energy	N/A	Cert-ID: 170741769 (NB 0297)
22096 Endo Cryo probe straight Ø 0.9 mm 764014986PA02CRYONR	Class IIb - Active therapeutic devices intended to administer or exchange energy	N/A	Cert-ID: 170741769 (NB 0297)
40300 Bimanual Irrigation/Aspiration Set 764014986PA04IA8A	Class IIa - Surgically invasive device intended for short-term use	N/A	Cert-ID: 170741769 (NB 0297)
40301 21G Bimanual irrigation (blue) 764014986PA04IA8A	Class IIa - Surgically invasive device intended for short-term use	N/A	Cert-ID: 170741769 (NB 0297)
40302 21G Bimanual aspiration (purple) 764014986PA04IA8A	Class IIa - Surgically invasive device intended for short-term use	N/A	Cert-ID: 170741769 (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
40400 I/A Monomanual handpiece 764014986PA04IA8A	Class IIa - Non-invasive devices intended for channelling body liquids, cells or tissues, liquids	N/A	Cert-ID: 170741769 (NB 0297)
40401 19G 60° 2mm I/A tip metal bent 764014986PA04IA8A	Class IIa - Surgically invasive device intended for short-term use	N/A	Cert-ID: 170741769 (NB 0297)
40402 19G I/A tip metal straight 764014986PA04IA8A	Class IIa - Surgically invasive device intended for short-term use	N/A	Cert-ID: 170741769 (NB 0297)
40403 19G I/A tip metal angled 764014986PA04IA8A	Class IIa - Surgically invasive device intended for short-term use	N/A	Cert-ID: 170741769 (NB 0297)
40404 19G I/A tip silicone straight 764014986PA04IA8A	Class IIa - Surgically invasive device intended for short-term use	N/A	Cert-ID: 170741769 (NB 0297)
40405 19G I/A tip silicone angled 764014986PA04IA8A	Class IIa - Surgically invasive device intended for short-term use	N/A	Cert-ID: 170741769 (NB 0297)
40411 20G I/A tip silicone straight 764014986PA04IA8A	Class IIa - Surgically invasive device intended for short-term use	N/A	Cert-ID: 170741769 (NB 0297)
40412 20G I/A tip silicone angled 764014986PA04IA8A	Class IIa - Surgically invasive device intended for short-term use	N/A	Cert-ID: 170741769 (NB 0297)
40416 22G I/A tip silicone straight 764014986PA04IA8A	Class IIa - Surgically invasive device intended for short-term use	N/A	Cert-ID: 170741769 (NB 0297)
40417 22G I/A tip silicone angled 764014986PA04IA8A	Class IIa - Surgically invasive device intended for short-term use	N/A	Cert-ID: 170741769 (NB 0297)
15200 2 step vitrectomy cannula system 20G 60° sterile 764014986PA06VCSFM	Class IIa - Surgically invasive device intended for short-term use	N/A	Cert-ID: 170741769 (NB 0297)
15201 2 step vitrectomy cannula system 20G sterile bulb 764014986PA06VCSFM	Class IIa - Surgically invasive device intended for short-term use	N/A	Cert-ID: 170741769 (NB 0297)
15500 2 step vitrectomy cannula system 23G sterile 764014986PA06VCSFM	Class IIa - Surgically invasive device intended for short-term use	N/A	Cert-ID: 170741769 (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
15501 2 step vitrectomy cannula system 23G sterile bulb 764014986PA06VCSFM	Class IIa - Surgically invasive device intended for short-term use	N/A	Cert-ID: 170741769 (NB 0297)
15550 1 step vitrectomy cannula system 23G sterile bulb, lance cut 764014986PA06VCSFM	Class IIa - Surgically invasive device intended for short-term use	N/A	Cert-ID: 170741769 (NB 0297)
15555 1 step vitrectomy cannula system vitreous herna 23G sterile bulb, lance cut 764014986PA06VCSFM	Class IIa - Surgically invasive device intended for short-term use	N/A	Cert-ID: 170741769 (NB 0297)
15560 1 step vitrectomy cannula system 23G sterile knife cut 764014986PA06VCSFM	Class IIa - Surgically invasive device intended for short-term use	N/A	Cert-ID: 170741769 (NB 0297)
15601 2 step vitrectomy cannula system sterile 25G bulb 764014986PA06VCSFM	Class IIa - Surgically invasive device intended for short-term use	N/A	Cert-ID: 170741769 (NB 0297)
15650 1 step vitrectomy cannula system 25G sterile bulb lance cut 764014986PA06VCSFM	Class IIa - Surgically invasive device intended for short-term use	N/A	Cert-ID: 170741769 (NB 0297)
15701 2 step vitrectomy cannula system sterile 27G bulb 764014986PA06VCSFM	Class IIa - Surgically invasive device intended for short-term use	N/A	Cert-ID: 170741769 (NB 0297)
15750 1 step vitrectomy cannula system sterile 27G bulb, lance cut 764014986PA06VCSFM	Class IIa - Surgically invasive device intended for short-term use	N/A	Cert-ID: 170741769 (NB 0297)
17100 Silicone oil aspiration adapter sterile 23G – 27G 764014986PA06VCSFM	Class I devices placed on the market in sterile condition	N/A	Cert-ID: 170741769 (NB 0297) Amendment I(s) to Cert-ID 170741769 2019-03-08 EN (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
10102 Test chamber set of 2 pieces	Class I devices placed on the market in non sterile condition	N/A	N/A - Device did not require a Notified Body certificate under Directives
10115 Stainless key straight	Class I devices placed on the market in non sterile condition	N/A	N/A - Device did not require a Notified Body certificate under Directives
10116 Stainless key bent	Class I devices placed on the market in non sterile condition	N/A	N/A - Device did not require a Notified Body certificate under Directives

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023-12-08	Cert-ID: 170741769	Initial issue