

MicroVention Europe SARL

30 bis, rue du Vieil Abreuveir
78100 Saint-Germain-en-Laye
France

Date: 2024-02-29

Notified Body Confirmation Letter

Reference: 1000168275

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:

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78100 Saint-Germain-en-Laye
France

SRN: FR-MF-000004449

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that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

A handwritten signature in blue ink, appearing to be 'Lena Breslauer'.

i.A Lena Breslauer
Regulatory Affairs Manager

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Email: lena.breslauer@dqs.de

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
FRED™ Flow Re-Direction Endoluminal Device FRED Jr.™ Flow Re-Direction Endoluminal Device FRED X™ Flow Re-Direction Endoluminal Device FRED Omega™ Flow Re-Direction Endoluminal Device Basic UDI-DI: 37015174FREDHU	Class III	N/A	487703 MR2 502357 MRA NB 0297
LifePearl Microspheres Basic UDI-DI: 37015174LIFEPEARLSB	Class III	N/A	487703 MR2 536956 MRA NB 0297
BioPearl Microspheres Basic UDI-DI: 37015174BIOPEARLPB	Class III	N/A	487703 MR2 545898 MRA NB 0297
CASPER™ Carotid Stent System CASPER™ X Carotid Stent System Roadsaver™ Carotid Stent System Roadsaver™ X Carotid Stent System Basic UDI-DI: 37015174ROADSAVERCASPER9Y	Class III	N/A	487703 MR2 514729 MRA NB 0297
ERIC™ Retrieval Device Basic UDI-DI: 37015174ERICHX	Class III	N/A	487703 MR2 512594 MRA NB 0297
Empro™ Embolic Protection System Nanoparasol™ Embolic Protection System Basic UDI-DI: 37015174EPRONANOPARASOLP5	Class III	N/A	487703 MR2 524858 MRA NB 0297
Aspiration Syringe Kit Aspiration Tubing Kit Basic UDI-DI: 37015174ASPIRATIONKITS7K	Class I devices placed on the market in sterile condition	N/A	487703 MR2 NB 0297
WEB Aneurysm Embolization System Basic UDI-DI: 37015174WEBAEDDR	Class III	N/A	487703 MR2 535861 MRA 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
SOFIA Distal Access Catheter SOFIA PLUS Catheter SOFIA EX Catheter SOFIA Flow Catheter SOFIA Flow PLUS Catheter SOFIA Select Catheter SOFIA Guiding Catheter Basic UDI-DI: 37015174SOFIAJ9	Class III	N/A	487703 MR2 487703 MRA NB 0297
HydroPearl Microspheres Basic UDI-DI: 37015174HYDROPEARL7K	Class IIb	N/A	487703 MR2 NB 0297
Renzan Peripheral Vascular Stent System Basic UDI-DI: 37015174RENZANJH	Class IIb	N/A	487703 MR2 NB 0297
PHIL™ Liquid Embolic System Basic UDI-DI: 37015174PHILKC	Class III	N/A	487703 MR2 517356 MRA NB 0297
LVIS™ Intraluminal Support Device LVIS™ Jr. Intraluminal Support Device LVIS™ EVO™ Intraluminal Support Device LVIS™ X™ Intraluminal Support Device LVIS™ Jr. X™ Intraluminal Support Device LVIS™ EVO™ X™ Intraluminal Support Device Basic UDI-DI: 37015174LVISM4	Class III	N/A	487703 MR2 490690 MRA 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

Confirmation Letter Revision History



Date	NB internal reference traceable to each version of the letter	Action
2024-02-29	1000168275	Initial issue