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

Ovesco Endoscopy AG

Friedrich-Miescher-Straße 9
72076 Tübingen
Germany

Date: 2024-11-04

Notified Body Confirmation Letter
Reference: 1000203888

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:

Ovesco Endoscopy AG

Friedrich-Miescher-Straße 9
72076 Tübingen
Germany

SRN: DE-MF-000006426

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that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

Lena Breslauer
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
AqaNife (426020631 RSCT002 6W)	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 50970-16-05; NB 0124
ArgoCap (426020631 RSCT006 76)	Class I devices placed on the market in sterile condition	N/A	Certificate 50970-16-05; NB 0124
AWC (426020631 RSCT005 74)	Class IIa	N/A	Certificate 50970-16-05; NB 0124
BARS Set (426020631 OTSC002 7H)	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 50970-16-05; NB 0124
BARS Anchor silver (426020631 OTSC002 7H)	Class I devices placed on the market in sterile condition	N/A	Certificate 50970-16-05; NB 0124
BARS Anchor black (426020631 OTSC002 7H)	Class I devices placed on the market in sterile condition	N/A	Certificate 50970-16-05; NB 0124
Coag Dissector (426020631 RSCT001 6U)	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 50970-16-05; NB 0124
BougieCap (426020631 REMV004 58)	Class I devices placed on the market in sterile condition	N/A	Certificate 50970-16-05; NB 0124
colonic FTRD Set (426020631 FTRD001 2J)	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 50970-16-05; NB 0124
diagnostic FTRD Set (426020631 FTRD001 2J)	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 50970-16-05; NB 0124
Fistula Brush (426020631 EPIN002 XF	Class I devices placed on the market in sterile condition	N/A	Certificate 50970-16-05; NB 0124
FTRD Grasper (426020631 EPIN004 XK)	Class I devices placed on the market in sterile condition	N/A	Certificate 50970-16-05; NB 0124
FTRD Marking Probe (426020631 FTRD001 2J	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 50970-16-05; NB 0124

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
colonic FTRD prOVE Cap (426020631 FTRD002 2L)	Class I devices placed on the market in sterile condition	N/A	Certificate 50970-16-05; NB 0124
gastroduodenal FTRD prOVE Cap (426020631 FTRD002 2L)	Class I devices placed on the market in sterile condition	N/A	Certificate 50970-16-05; NB 0124
gastroduodenal FTRD (426020631 FTRD001 2J)	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 50970-16-05; NB 0124
HemoPill acute (426020631 HEMP001 WB)	Class IIa	N/A	Certificate 50970-16-05; NB 0124
HemoPill monitor (426020631 HEMP002 WD)	Class IIa	N/A	Certificate 50970-16-05; NB 0124
HemoPill Receiver (426020631 HEMP003 WF)	Class IIa	N/A	Certificate 50970-16-05; NB 0124
LiftUp (426020631 RSCT004 72)	Class IIa	N/A	Certificate 50970-16-05; NB 0124
LiftUp Kit (426020631 RSCT004 72)	Class IIa	N/A	Certificate 50970-16-05; NB 0124
mini OTSC System Set (426020631 OTSC001 7F)	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 50970-16-05; NB 0124
OTSC Anchor (426020631 EPIN001 XD)	Class I devices placed on the market in sterile condition	N/A	Certificate 50970-16-05; NB 0124
OTSC Twin Grasper (426020631 EPIN003 XH)	Class I devices placed on the market in sterile condition	N/A	Certificate 50970-16-05; NB 0124
OTSC Proctology (426020631 PROC001 5S)	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 50970-16-05; NB 0124
OTSC System Set (426020631 OTSC001 7F)	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 50970-16-05; NB 0124
OTSC neo System Set (426020631 OTSC001 7F)	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 50970-16-05; NB 0124

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
OTSG Xcavator (426020631 EPIN005 XM)	Class I devices placed on the market in sterile condition	N/A	Certificate 50970-16-05; NB 0124
remOVE DC Cutter Set (426020631 REMV002 54)	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 50970-16-05; NB 0124
remOVE DC Impulse (426020631 REMV001 52)	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 50970-16-05; NB 0124
remOVE FBR Set (426020631 REMV003 56)	Class I devices placed on the market in sterile condition	N/A	Certificate 50970-16-05; NB 0124
stentfix OTSC System Set (426020631 OTSC003 7K)	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 50970-16-05; NB 0124
Traction Polypectomy Snare (426020631 RSCT003 6Y)	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 50970-16-05; NB 0124
OTSC Proctology Anchor (426020631 EPIN001 XD)	Class I devices placed on the market in sterile condition	N/A	Certificate 50970-16-05; NB 0124

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
2024-09-16	1000179201	Initial issue
2024-11-04	1000203888	Correction of MDR Device Classification from Class IIb implantable non-WET device to Class IIb excluding Class IIb implantable non-WET for following clip devices: BARS Set, colonic FTRD Set, diagnostic FTRD Set, gastroduodenal FTRD, mini OTSC System Set, OTSC Proctology, OTSC System Set, OTSC neo System Set, stentfix OTSC System Set