



EU Quality Management Certificate



This is to certify that the company

FUJIFILM medwork GmbH

Medworking 1
91315 Höchstadt a.d. Aisch
Germany

SRN: DE-MF-000008444

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. 230521 MDR2017Q

Certificate ID 1000255307

Effective date 2025-12-11

Expiry date 2028-10-01

Frankfurt am Main, 2025-12-11



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlgs.de
BS-MDR-094

DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director



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: DE-MF-000008444

Certificate ID: 1000255307

Device categories and variants covered by this certificate:

Device category: **MDN 1203 - Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools**
Product name: Stone extraction balloon
Risk classification: Is
Basic-UDI-DI: 4044503056113U
Intended purpose: **Stone extraction balloons** are used for endoscopic extraction of stones and sludge from the bile and pancreatic duct and for injection of contrast medium into the bile and pancreatic duct.

Device category: **MDA 0312 - Other active non-implantable surgical devices**
Product name: Polypectomy snare
Risk classification: Polypectomy snare with injection needle
Basic-UDI-DI: IIb
40445030564349
Intended purpose: **Polypectomy snares** are used for endoscopic tissue resection in the upper and lower gastrointestinal tract.

Device category: **MDN 1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis**
Product name: Application catheter
Risk classification: Is
Basic-UDI-DI: 404450300100ZQ
Intended purpose: **Application catheters** are used to apply hemostatic agents like synthetic peptide material or aqueous peptide solutions in endoscopic procedures in the upper and lower gastrointestinal tract..

Device category: **MDN 1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis**
Product name: ERCP-Catheter
Risk classification: Is
Basic-UDI-DI: 40445030561748
Intended purpose: **ERCP catheters** are used for endoscopic cannulation of the papilla and application of contrast medium into the biliary, pancreatic and hepatic ducts.



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Device category:

MDN 1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis

Product name:

EUS-FNA needle

EUS-FNB needle

Risk classification:

IIa

Basic-UDI-DI:

4044503017813S

Intended purpose:

The **EUS-FNA/FNB needles** are used with a curvilinear echoendoscope for fine needle aspiration and biopsy of submucosal and extramural gastrointestinal lesions or for delivery of injectable materials.

Device category:

MDN 1208 - Non-active non-implantable instruments

Product name:

Polypectomy snare, cold

IIa

Basic-UDI-DI:

4044503060483U

Intended purpose:

Polypectomy snares are used for endoscopic tissue resection in the upper and lower gastrointestinal tract.

Device category:

MDA 0312 - Other active non-implantable surgical devices

Product name:

Papillotome

Risk classification:

Papillotome + guide wire

IIb

Basic-UDI-DI:

40445030564247

Intended purpose:

Papillotomes are used for papillotomy, endoscopic cannulation of the papilla and visualisation of the ductal system by means of contrast medium application.

Device category:

MDN 1203 - Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools

Product name:

Guiding catheter

Risk classification:

Is

Basic-UDI-DI:

4044503060493W

Intended purpose:

Guiding catheters are used for endoscopic stent delivery for drainage of the biliary system.

Device category:

MDN 1203 - Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools

Product name:

Delivery system

Risk classification:

Is

Basic-UDI-DI:

4044503056484K

Intended purpose:

Delivery systems are used for endoscopic stent delivery for drainage of the biliary system.



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Device category:	MDN 1203 - Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools
Product name:	Pusher
Risk classification:	Is
Basic-UDI-DI:	4044503060503F
Intended purpose:	Pushers are used for endoscopic stent delivery for drainage of the biliary system.

Examinations and tests performed:

230521_A210021MED_01 dated 2022-10-28
230521_A213086MED_01 BAL1 Series dated 2023-09-16
230521_A210021MED_01 POL1 Series dated 2024-05-18
230521_A214650MED Application catheter dated 2024-07-30
230521_A216053MED_02 EUS-FNA needle / EUS-FNB needle dated 2025-03-11
230521_A210021MED_04 POL1-Z-Series dated 2025-03-24
230521_A210021MED_ Papillotomes / Sphincterotomes dated 2025-06-08

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

In case of products that are placed on the market in sterile condition, the involvement of the Notified Body in the conformity assessment procedure is limited to the aspects of manufacture concerned with securing and maintaining sterile condition.

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2023-10-02	170780024	Addition of Polypectomy Snares
02	2024-05-23	1000171787	Addition of Application catheter, Certificate correction of typo files and change of address
03	2024-08-08	1000191195	Addition of ERCP-Catheter
04	2024-08-29	1000195468	Addition of EUS-FNA needle / EUS-FNB needle
05	2025-03-20	1000204042	Addition of Polypectomy snares
06	2025-04-03	1000231212	Addition of Papillotome and Papillotome + guide wire
07	2025-06-12	1000232656	Addition of Guiding catheter, Delivery system, Pusher