EU Quality Management Certificate

This is to certify that the company

FUJIFILM medwork GmbH

Medworkring 1
91315 Höchstadt a.d. Aisch
Germany

SRN: DE-MF-0000084444

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	1000195468
Effective date	2024-08-29
Expiry date	2028-10-01
Frankfurt am Main,	2024-08-29

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

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)

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.

420.90 Version 6.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-0000084444
Certificate ID: 1000195468

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 Polypectomy snare with injection needle
Risk classification:	IIb
Basic-UDI-DI:	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.

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

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Further conditions for or limitations to the validity of the certificate:
The manufacturer's quality management system is subject to periodic surveillance in accordance with Annex IX, Chapter 1, Section 3.
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