EU Quality Management Certificate

This is to certify that the company

FUJIFILM medwork GmbH

Medworkring 1
91315 Höchstadt
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. Limitations to this certificate are listed in the Annex.

For placing of devices of class IIa, IIb or III 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	170780024
Effective date	2023-10-02
Expiry date	2028-10-01
Frankfurt am Main,	2023-10-02

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 this certificate can only be verified by the QR-code.

420.90 Version 5.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-0000084444
Certificate ID: 170780024

Device categories covered by this certificate:

Device category:	**G03050101 – Digestive endoscopy, retrieval balloon device**
Risk classification:	Is
Intended purpose:	Stone extraction balloons are used for endoscopic extraction of stones and sludge from the bile and pancreatic duct and to clear an occlusion of the bile duct after application of contrast medium.

Examinations and tests performed:
230521_A210021MED_01 dated 2022-10-28
230521_A213086MED_01 BAL1 Series dated 2023-09-16

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
n/a	n/a	n/a	n/a