



CERTIFICATE



This is to certify that the company

FUJIFILM medwork GmbH

Medworkring 1
91315 Höchststadt a.d. Aisch
Germany

with the organizational units/sites as listed in the annex
has implemented and maintains a **Quality Management System**.

Scope:

Sterile:

Design, Development, Manufacturing, Distribution of
BILIARY BALLOON CATHETERS - HIGH PRESSURE, BILIARY TUBES,
BRONCHOSCOPIC INSTRUMENTARY - OTHERS, DIGESTIVE ENDOSCOPY - HAEMOSTASIS CLIPS,
DIGESTIVE ENDOSCOPY - MONOLUME NEEDLES, DIGESTIVE ENDOSCOPY - RETRIEVAL BALLOON DEVICES,
DIGESTIVE ENDOSCOPY - - RETRIEVAL BASKET DEVICES - NON-REVOLVING / REVOLVING,
DIGESTIVE ENDOSCOPY - RETRIEVAL DEVICES - OTHERS,
ERCP CANNULAS - ONE-WAY - STANDARD TIP / TAPERED TIP/ OTHERS,
ERCP CANNULAS - MORE WAYS - TAPERED TIP,
ERCP AND SPHINCTEROTOMY DEVICES - OTHERS, GASTROINTESTINAL DEVICES - OTHERS,
GASTROINTESTINAL ENDOSCOPY - COLD BIOPSY FORCEPS,
GASTROINTESTINAL ENDOSCOPY - EXTRACTION FORCEPS - SINGLE-USE,
GASTROINTESTINAL ENDOSCOPY DEVICES - ACCESSORIES - GUIDE WIRE FIXATION / VALVES,
GASTROINTESTINAL ENDOSCOPY DEVICES - OTHERS, LITHOTRIPSY DEVICES (non-active)
PAPILLOTOMES / SPHINCTEROTOMES - BILUMEN / TRILUMEN OR MORE / OTHERS,
POLYPECTOMY SNARES - REVOLVING / NON-REVOLVING / OTHERS

Non-sterile:

Design, Development, Manufacturing, Distribution of
GASTROINTESTINAL ENDOSCOPY, BITE BLOCKS
LITHOTRIPSY DEVICES (non-active)
DIGESTIVE ENDOSCOPY, RETRIEVAL DEVICES - OTHERS
GASTROINTESTINAL ENDOSCOPY DEVICES - ACCESSORIES

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2018
ISO 13485 : 2016

Certificate registration no. 230521 MP2016
Certificate unique ID 1000222025
Effective date 2025-03-10
Expiry date 2028-03-09
Frankfurt am Main 2025-02-26



DQS IS A MEMBER OF



DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, info-med@dqs.de

The validity of the certification can only be verified by the QR-code.





Annex to certificate
Certificate registration No.: 230521 MP2016
Certificate unique ID: 1000222025
Effective date: 2025-03-10

FUJIFILM medwork GmbH

Medworkring 1
91315 Höchststadt a.d. Aisch
Germany

Location

549775
FUJIFILM medwork GmbH
Medworkring 1
91315 Höchststadt
Germany

Scope

Sterile:

Design, Development, Manufacturing, Distribution of
BILIARY BALLOON CATHETERS - HIGH PRESSURE,
BILIARY TUBES,
BRONCHOSCOPIC INSTRUMENTARY – OTHERS,
DIGESTIVE ENDOSCOPY - HAEMOSTASIS CLIPS,
DIGESTIVE ENDOSCOPY - MONOLUME NEEDLES,
DIGESTIVE ENDOSCOPY - RETRIEVAL BALLOON
DEVICES,
DIGESTIVE ENDOSCOPY - - RETRIEVAL BASKET
DEVICES - NON-REVOLVING / REVOLVING,
DIGESTIVE ENDOSCOPY - RETRIEVAL DEVICES –
OTHERS,
ERCP CANNULAS - ONE-WAY - STANDARD TIP /
TAPERED TIP/ OTHERS,
ERCP CANNULAS - MORE WAYS - TAPERED TIP,
ERCP AND SPHINCTEROTOMY DEVICES – OTHERS,
GASTROINTESTINAL DEVICES – OTHERS,
GASTROINTESTINAL ENDOSCOPY – COLD BIOPSY
FORCEPS,
GASTROINTESTINAL ENDOSCOPY - EXTRACTION
FORCEPS - SINGLE-USE,
GASTROINTESTINAL ENDOSCOPY DEVICES –
ACCESSORIES – GUIDE WIRE FIXATION / VALVES,
GASTROINTESTINAL ENDOSCOPY DEVICES – OTHERS,
LITHOTRIPSY DEVICES (non-active)
PAPILLOTOMES / SPHINCTEROTOMES – BILUMEN /
TRILUMEN OR MORE / OTHERS,
POLYPECTOMY SNARES – REVOLVING / NON-
REVOLVING / OTHERS

Non-sterile:

Design, Development, Manufacturing, Distribution of
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OTHERS
GASTROINTESTINAL ENDOSCOPY DEVICES -
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FUJIFILM medwork GmbH

Medworkring 1
91315 Höchststadt a.d. Aisch
Germany

Location

549759
FUJIFILM medwork GmbH
Medworkring 2
91315 Höchststadt
Germany

Scope

Sterile:

Design, Development, Manufacturing, Distribution of
BILIARY BALLOON CATHETERS - HIGH PRESSURE,
BILIARY TUBES,
BRONCHOSCOPIC INSTRUMENTARY – OTHERS,
DIGESTIVE ENDOSCOPY - HAEMOSTASIS CLIPS,
DIGESTIVE ENDOSCOPY - MONOLUME NEEDLES,
DIGESTIVE ENDOSCOPY - RETRIEVAL BALLOON
DEVICES,
DIGESTIVE ENDOSCOPY - - RETRIEVAL BASKET
DEVICES - NON-REVOLVING / REVOLVING,
DIGESTIVE ENDOSCOPY - RETRIEVAL DEVICES –
OTHERS,
ERCP CANNULAS - ONE-WAY - STANDARD TIP /
TAPERED TIP/ OTHERS,
ERCP CANNULAS - MORE WAYS - TAPERED TIP,
ERCP AND SPHINCTEROTOMY DEVICES – OTHERS,
GASTROINTESTINAL DEVICES – OTHERS,
GASTROINTESTINAL ENDOSCOPY – COLD BIOPSY
FORCEPS,
GASTROINTESTINAL ENDOSCOPY - EXTRACTION
FORCEPS - SINGLE-USE,
GASTROINTESTINAL ENDOSCOPY DEVICES –
ACCESSORIES – GUIDE WIRE FIXATION / VALVES,
GASTROINTESTINAL ENDOSCOPY DEVICES – OTHERS,
LITHOTRIPTY DEVICES (non-active)
PAPILLOTOMES / SPHINCTEROTOMES – BILUMEN /
TRILUMEN OR MORE / OTHERS,
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