



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

FUJIFILM medwork GmbH

Medworking 1
91315 Höchststadt
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

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

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Medical devices for flexible gastroenterological and surgical endoscopy according to annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	230521 MR2
Certificate unique ID	170768766
Effective date	2020-04-14
Expiry date	2024-02-27
Frankfurt am Main	2020-04-14

DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.



Annex to certificate
Certificate registration No.: 230521 MR2
Certificate unique ID: 170768766
Effective date: 2020-04-14



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Product family	Product	Class
Stone Extraction Balloon	BAL1-Series	Is
Stone Extraction Basket	BAS1,3-Series	Is
Biopsy Forceps	BIO1-Series	IIa
ERCP-Catheter	CAN1-Series	Is
Dilation Instrument	DIL1-Series	Is
Foreign Body Retrieval Instrument	FOR1-Series	Is
Injection needle	INJ1-Series	IIa
Lithotripter Basket	LIT1,3-Series	Is
ERCP Towel	MIS1-Series	Is
Papillotome	PAP1-Series	IIb
Polypectomy Snare	POL1,2-Series	IIb
Biliary Stent	PRO1-T2,C2-Series	IIb
Guiding catheter / Pusher / Endoprosthesis delivery system	PRO1-S1,K1,P1,2-Series	Is
Lavage catheter / Spraying Catheter	SPE1-Series	Is
Clip applicator	SPE1-X-Series	IIb
easycure Locking Device	SPE1-Y7-Series	Is
Endoscopic Valve	VAL1-Series	Is
Guide Wire	WIR1-Series	Is
Polypectomy Snare	POL1-Z-Series	IIa