



CERTIFICATE



This is to certify that the company

RUDOLF Medical GmbH + Co. KG

Zollerstrasse 1 78567 Fridingen Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a Quality Management System.

Scope:

Development, manufacture, sales and service of reusable surgical instruments, laparoscopic instruments, resectoscopes, retractors, endoscopes, suction and irrigation instruments, osteosynthesis implants, HF instruments, sterilization containers and 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:

EN ISO 13485:2016 / A11 : 2021

ISO 13485: 2016

Certificate registration no.

492576 MP2021

Certificate unique ID

1000186807

Effective date

2024-07-06

Expiry date

2027-07-05

Frankfurt am Main

2024-07-06



DQS Medizinprodukte GmbH

Melena





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S. Kuelyn.

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Annex to certificate

Certificate registration No.: 492576 MP2021

Certificate unique ID: 1000186807

Effective date: 2024-07-06

RUDOLF Medical GmbH + Co. KG

Zollerstrasse 1 78567 Fridingen Germany

Location

537402 **RUDOLF Medical GmbH + Co. KG** Zollerstrasse 1

78567 Fridingen Germany

537401 **RUDOLF Medical GmbH + Co. KG** Tuttlingerstr. 4 78567 Fridingen Germany

Scope

Development, manufacture, sales and service of reusable surgical instruments, laparoscopic instruments, resectoscopes, retractors, endoscopes, suction and irrigation instruments, osteosynthesis implants, HF instruments, sterilization containers and accessories

Manufacture and service of reusable surgical instruments, laparoscopic instruments, resectoscopes, retractors, endoscopes, suction and irrigation instruments, osteosynthesis implants, HF instruments, sterilization containers and accessories