CERTIFICATE

This is to certify that the company

RUDOLF

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 of certification:
Development, manufacture, sales, and service of reusable surgical instruments, laparoscopic instruments, resectoscopes, retractors, endoscopes, suction-irrigation instruments, osteosynthesis implants, HF instruments, sterilization containers and accessories.
-AUS (a), CND, JPN, USA (a,b,c,d)

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:

ISO 13485 : 2016

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

Certificate registration no.	492576 MDSAP16
Certificate unique ID	1000188559
Effective date	2024-07-30
Expiry date	2027-07-29
Frankfurt am Main	2024-07-22

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Marc Goedecke
Product Manager

Annex to certificate
Certificate registration No.: 492576 MDSAP16
Certificate unique ID: 1000188559
Effective date: 2024-07-30

RUDOLF Medical GmbH + Co. KG

Zollerstrasse 1
78567 Fridingen
Germany

Audited site	REPs FEI No.: site scope and country-specific requirements
537402 **RUDOLF Medical GmbH + Co. KG** **Verwaltung** Zollerstrasse 1 78567 Fridingen Germany	Development, manufacture, sales, and service of reusable surgical instruments, laparoscopic instruments, resectoscopes, retractors, endoscopes, suction-irrigation instruments, osteosynthesis implants, HF instruments, sterilization containers and accessories. -**AUS (a), CND, JPN, USA (a,b,c,d)** **REPs FEI No.: F000639**
537401 **RUDOLF Medical GmbH + Co. KG** **Produktion** Tuttlingerstr. 4 78567 Fridingen Germany	Manufacture and service of reusable surgical instruments, laparoscopic instruments, resectoscopes, retractors, endoscopes, suction-irrigation instruments, osteosynthesis implants, HF instruments, sterilization containers and accessories. **- AUS (a), CND, JPN, USA (a,b,c,d)** **REPs FEI No.: F001971**

Annex to certificate
Certificate registration No.: 492576 MDSAP16
Certificate unique ID: 1000188559
Effective date: 2024-07-30

RUDOLF Medical GmbH + Co. KG

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78567 Fridingen
Germany

Full references of country-specific requirements of MDSAP participating Regulatory Authorities

Abbreviation	Jurisdiction	Reference
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009
CND	Canada	Medical Devices Regulations – Part 1- SOR 98/282 Medical Devices Regulations – Part 1.1 – SOR 98/282 (as applicable)
JPN	Japan	MHLW Ministerial Ordinance 169, Article 4 to Article 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821