



CERTIFICATE



This is to certify that the company

TUDOLF

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:

The development, manufacture, service and sale of surgical instruments, equipment and following medical devices;

Suction systems, irrigation systems, insufflators, light sources, camera systems, image storage/transmission systems, equipment trolleys, self retaining retractors, morcellator systems with reusable blade attachments, HFsurgical equipment. non-active implants, sterilization support systems and endoscopes.

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 : 2016

ISO 13485: 2016

Certificate registration no. 492576 MP2016

Certificate unique ID 170774649

Effective date 2021-07-16

Expiry date 2024-07-15

Frankfurt am Main 2021-07-16



DQS Medizinprodukte GmbH

J. Mbleuc

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Dr. Thomas Feldmann Head of Certification Body







Annex to certificate

Certificate registration No.: 492576 MP2016

Certificate unique ID: 170774649

Effective date: 2021-07-16

RUDOLF Medical GmbH + Co. KG

Zollerstrasse 1 78567 Fridingen Germany

Location

537401 RUDOLF Medical GmbH + Co. KG Produktion

Tuttlingerstr. 4 78567 Fridingen Germany

Scope

The development, manufacture, service and sale of surgical instruments, equipment and following medical devices;

Suction systems, irrigation systems, insufflators, light sources, camera systems, image storage/transmission systems, equipment trolleys, self retaining retractors, morcellator systems

with reusable blade attachments, HFsurgical equipment. non-active implants, sterilization support systems and endoscopes.

537402 RUDOLF Medical GmbH + Co. KG Verwaltung

Zollerstrasse 1 78567 Fridingen Germany The development, manufacture, service and sale of surgical instruments, equipment and following medical devices;

Suction systems, irrigation systems, insufflators, light sources, camera systems, image storage/transmission systems, equipment trolleys, self retaining retractors, morcellator systems

with reusable blade attachments, HFsurgical equipment. non-active implants, sterilization support systems and endoscopes.

