EU Quality Management Certificate

This is to certify that the company

RUDOLF

RUDOLF Medical GmbH + Co. KG

Zollerstrasse 1
78567 Fridingen
Germany

SRN: DE-MF-000005515

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745
Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	492576 MDR2017Q
Certificate ID	1000175019
Effective date	2025-02-28
Expiry date	2030-02-27
Frankfurt am Main,	2025-02-28

Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745
of the Council concerning medical devices with the Identification Number 0297.
The validity of the certification can only be verified by the QR-code.

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420.90 Version 7.0

Device categories and variants covered by this certificate:

Device category:	**1207 - non-active non-implantable diagnostic devices**
Product name:	endoscopes
Risk classification:	IIa
Basic-UDI-DI:	4049356TD-200GY
Intended purpose:	Endoscopes are intended to illuminate and visualize inner anatomic structures during diagnostic and surgical procedures.

Examinations and tests performed:
492576_ A213923MED_01 dated 2024-12-26
492576_ A212590MED_02 TD-200 endoscopes dated 2024-11-29

Further conditions for or limitations to the validity of the certificate:
n/a

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
n/a	n/a	n/a	n/a