RUDOLF
BECAUSE WE CARE

Declaration of Conformity
Konformitätserklärung

We / *Wir*

RUDOLF Medical GmbH + CO. KG

Zollerstrasse 1
78567 Fridingen
Germany

SRN: DE-MF-000005515

declare under our sole responsibility that the following products

erklären in alleiniger Verantwortung, dass die unten aufgeführten Artikel

Basic UDI-DI	Device	EMDN	Risk Class
4049356TD-200GY	Endoscopes	Z12029009	2a

See attached device list. / *Siehe angehängte Artikelliste.*

with the intended purpose / mit der Zweckbestimmung

Endoscopes are intended to illuminate and visualize inner anatomic structures during diagnostic and surgical procedures.

Indications:

- Laparoscopes are used for the visual examination and for performing minimally invasive surgery in the abdominal cavity.
- ENT endoscopes (Otoscopes, Sinuscopes) are used for the visual examination and diagnosis of diseases in the ear, nose, and throat areas.
- Cystoscopes are used for the visual examination and diagnosis of diseases of the urinary bladder and urethra, whereby the endoscope is mounted to a shaft system.
- Hysteroscopes are used for the visual examination and diagnosis of diseases of the uterus, whereby the endoscope is mounted to a shaft system.
- Arthroscopes are used for the visual examination and diagnosis of diseases at a joint.
- Uretero-renoscopes are used for the visual examination and diagnosis of diseases of the ureter and kidney. The working channel of the endoscope enables additional procedures with flexible and semi-rigid instruments.

Endoskope sind vorgesehen zur Beleuchtung und Visualisierung innerer anatomischer Strukturen bei diagnostischen und chirurgischen Eingriffen.

Indikationen:

- Laparoskope dienen der visuellen Untersuchung und Durchführung minimalinvasiver Operationen in der Bauchhöhle.
- HNO-Endoskope (Otoskope, Sinuskope) dienen der visuellen Untersuchung und Diagnose von Erkrankungen im Hals-, Nasen- und Ohrenbereich.
- Zystoskope dienen der visuellen Untersuchung und Diagnose von Erkrankungen der Harnblase und der Harnröhre, wobei das Endoskop mit einem Schaftsystem montiert wird.
- Hysteroskope dienen der visuellen Untersuchung und Diagnose von Erkrankungen der Gebärmutter, wobei das Endoskop mit einem Schaftsystem montiert wird.
- Arthroskope dienen der visuellen Untersuchung und Diagnose von Erkrankungen innerhalb eines Gelenks.
- Uretero-Renoskope dienen der visuellen Untersuchung und Diagnose von Erkrankungen des Harnleiters und der Niere. Der Arbeitskanal des Endoskops ermöglicht zusätzliche Verfahren mit flexiblen und halbstarren Instrumenten.

Digitally signed by Ermicev Alexandr
Date: 2026.01.19 11:54:37 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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Declaration of Conformity
Konformitätserklärung

are in conformity with the requirements of the

Medical Device Regulation (EU) 2017/745 Annex IX with Chapters I and III, and Section 4

Notified Body: DQS
Identification No: 0297

DQS Medizinprodukte GmbH
August-Schanz-Strasse 21
60433 Frankfurt am Main
Germany

The validity of the Declaration of Conformity corresponds to the current valid EC certificate – Full QA System, Annex IX of (EU) 2017/745.

mit den folgenden Anforderungen übereinstimmen.

Medizinprodukte-Verordnung (EU) 2017/745 Anhang IX mit Kapitel I, III und Abschnitt 4

Benannte Stelle: DQS
Kennnummer: 0297

DQS Medizinprodukte GmbH
August-Schanz-Strasse 21
60433 Frankfurt am Main
Germany

Die Gültigkeit der Konformitätserklärung entspricht der Geltungsdauer des aktuell gültigen EG-Zertifikates – vollständiges QM-System nach Anhang IX der (EU) 2017/745.

Name: i. V. Ayfer Bektas

Function: PRRC

Signature:

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Date of issue: 2025-04-01

Place of issue: Fridingen, Germany

Annexes

- Device List
- Product Standards and Guidances

EU Quality Management Certificate

This is to certify that the company

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.

420.90 Version 7.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000005515
Certificate ID: 1000175019

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

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TD-200 - endoscopes

2024-02-15

REF	Item Description	GTIN	GMDN-No	GMDN-Term	rule MDR	class MDR	TD_NO	IFU
AT127-030	ARTHROSCOPE, AUTOCLAVABLE 2.7 MM,30°,WL 110 MM	404935625935	34856	Rigid arthroscope, reusable	7	IIa	TD-200	243
AT140-000	ARTHROSCOPE, AUTOCLAVABLE 4.0 MM,0°,WL 175 MM	404935625943	34856	Rigid arthroscope, reusable	7	IIa	TD-200	243
AT140-030	ARTHROSCOPE, AUTOCLAVABLE 4,0 MM,30°,WL 175 MM	404935625944	34856	Rigid arthroscope, reusable	7	IIa	TD-200	243
AT140-070	ARTHROSCOPE, AUTOCLAVABLE 4,0 MM,70°,WL 175 MM	404935625949	34856	Rigid arthroscope, reusable	7	IIa	TD-200	243
EN127-000	OTOSCOPE,AUTOCLAVABLE, Ø 2.7 MM,DIRECTION OF VIEW 0°,	404935611062	44929	Otoscope, endoscopic	7	IIa	TD-200	243
EN127-030	OTOSCOPE,AUTOCLAVABLE, Ø 2.7 MM,DIRECTION OF VIEW 30°,	404935611063	44929	Otoscope, endoscopic	7	IIa	TD-200	243
EN127-100	SINUSCOPE,AUTOCLAVABLE, Ø 2.7 MM,DIRECTION OF VIEW 0°,	404935604361	37180	Rigid sinoscope	7	IIa	TD-200	243
EN127-130	SINUSCOPE,AUTOCLAVABLE, Ø 2.7 MM,DIRECTION OF VIEW 30°,	404935604362	37180	Rigid sinoscope	7	IIa	TD-200	243
EN127-170	SINUSCOPE,AUTOCLAVABLE, Ø 2.7 MM,DIRECTION OF VIEW 70°,	404935604363	37180	Rigid sinoscope	7	IIa	TD-200	243
EN140-000	SINUSCOPE,AUTOCLAVABLE, Ø 4 MM,DIRECTION OF VIEW 0°,	404935604367	37180	Rigid sinoscope	7	IIa	TD-200	243
EN140-030	SINUSCOPE,AUTOCLAVABLE, Ø 4 MM,DIRECTION OF VIEW 30°,	404935604368	37180	Rigid sinoscope	7	IIa	TD-200	243
EN140-045	SINUSCOPE,AUTOCLAVABLE, Ø 4 MM,DIRECTION OF VIEW 45°,	404935604369	37180	Rigid sinoscope	7	IIa	TD-200	243
EN140-070	SINUSCOPE,AUTOCLAVABLE, Ø 4 MM,DIRECTION OF VIEW 70°,	404935604370	37180	Rigid sinoscope	7	IIa	TD-200	243
EN140-100	OTOSCOPE,AUTOCLAVABLE, Ø 4 MM,DIRECTION OF VIEW 0°,	404935611064	44929	Otoscope, endoscopic	7	IIa	TD-200	243
EN140-130	OTOSCOPE,AUTOCLAVABLE, Ø 4 MM,DIRECTION OF VIEW 30°,	404935611065	44929	Otoscope, endoscopic	7	IIa	TD-200	243
EU107-012	URETERO-RENOSCOPE,AUTOCLAVABLE SEMIRIGID, Ø 6.0/7,5FR, WL 430MM, 12° WITH LATERAL OFFSET EYEPIECE	404935646620	37112	Rigid ureterorenoscope	7	IIa	TD-200	243
EU107-212	URETERO-RENOSCOPE,AUTOCLAVABLE SEMIRIGID, Ø 6.0/7,5FR, WL 430MM, 12° WITH LATERAL EYEPIECE	404935646898	37112	Rigid ureterorenoscope	7	IIa	TD-200	243
EU109-012	URETERO-RENOSCOPE,AUTOCLAVABLE SEMIRIGID, 8/9,8FR,12°,WL430MM, WITH LATERAL OFFSET EYEPIECE	404935601994	37112	Rigid ureterorenoscope	7	IIa	TD-200	243

TD-200 - endoscopes

REF	Item Description	GTIN	GMDN-No	GMDN-Term	rule MDR	class MDR	TD_NO	IFU
EU109-212	URETERO-RENOSCOPE,AUTOCLAVABLE SEMIRIGID, 8/9,8FR,12°,WL430MM, WITH LATERAL EYEPIECE	404935601996	37112	Rigid ureterorenoscope	7	IIa	TD-200	243
EU111-012	URETERO-RENOSCOPE,AUTOCLAVABLE SEMIRIGID,8.5/11.5FR,12°,WL430MM, WITH LATERAL OFFSET EYEPIECE	404935628826	37112	Rigid ureterorenoscope	7	IIa	TD-200	243
EU111-212	URETERO-RENOSCOPE,AUTOCLAVABLE SEMIRIGID,8.5 /11.5FR. ,12°,WL430MM, WITH LATERAL EYEPIECE	404935628828	37112	Rigid ureterorenoscope	7	IIa	TD-200	243
EU127-000	CYSTOSCOPE,AUTOCLAVABLE, 2.7 MM,0°,WORKING LENGTH 302 MM	404935622648	17145	Rigid cystoscope	7	IIa	TD-200	243
EU127-030	CYSTOSCOPE,AUTOCLAVABLE, 2.7 MM,30°,WORKING LENGTH 302 MM	404935622649	17145	Rigid cystoscope	7	IIa	TD-200	243
EU129-000	CYSTOSCOPE, AUTOCLAVABLE 2,9 MM,0°,WL 302 MM	404935622654	17145	Rigid cystoscope	7	IIa	TD-200	243
EU129-030	CYSTOSCOPE, AUTOCLAVABLE 2,9 MM,30°,WL 302 MM	404935622655	17145	Rigid cystoscope	7	IIa	TD-200	243
EU140-000	CYSTOSCOPE, AUTOCLAVABLE 4,0 MM,0°,WL 302 MM	404935622657	17145	Rigid cystoscope	7	IIa	TD-200	243
EU140-012	CYSTOSCOPE, AUTOCLAVABLE 4,0 MM,12°,WL 302 MM	404935622658	17145	Rigid cystoscope	7	IIa	TD-200	243
EU140-030	CYSTOSCOPE, AUTOCLAVABLE 4,0 MM,30°,WL 302 MM	404935622659	17145	Rigid cystoscope	7	IIa	TD-200	243
EU140-070	CYSTOSCOPE, AUTOCLAVABLE 4,0 MM,70°,WL 302 MM	404935622660	17145	Rigid cystoscope	7	IIa	TD-200	243
GY120-000	HYSTEROSCOPE, SEMIRIGID, AUTOCLAVABLE 2,0 MM,0°,WL 260 MM	404935618017	36628	Rigid fibreoptic hysteroscope	7	IIa	TD-200	243
GY120-030	HYSTEROSCOPE, SEMIRIGID, AUTOCLAVABLE, 2,0 MM, 30°, WL 260 MM	404935618018	36628	Rigid fibreoptic hysteroscope	7	IIa	TD-200	243
GY127-000	HYSTEROSCOPE, AUTOCLAVABLE 2,7 MM,0°,WL 302 MM	404935618019	36628	Rigid fibreoptic hysteroscope	7	IIa	TD-200	243
GY127-030	HYSTEROSCOPE, AUTOCLAVABLE 2,7 MM, 30°,WL 302 MM	404935618020	36628	Rigid fibreoptic hysteroscope	7	IIa	TD-200	243
GY127-070	HYSTEROSCOPE, AUTOCLAVABLE 2,7 MM,70°,WL 302 MM	404935618021	36628	Rigid fibreoptic hysteroscope	7	IIa	TD-200	243
GY129-000	HYSTEROSCOPE, AUTOCLAVABLE 2,9 MM,0°,WL 302 MM	404935618022	36628	Rigid fibreoptic hysteroscope	7	IIa	TD-200	243
GY129-030	HYSTEROSCOPE, AUTOCLAVABLE 2,9 MM,30°,WL 302 MM	404935618023	36628	Rigid fibreoptic hysteroscope	7	IIa	TD-200	243
GY140-000	HYSTEROSCOPE, AUTOCLAVABLE 4,0 MM,0°,WL 302 MM	404935618025	36628	Rigid fibreoptic hysteroscope	7	IIa	TD-200	243

TD-200 - endoscopes

REF	Item Description	GTIN	GMDN-No	GMDN-Term	rule MDR	class MDR	TD_NO	IFU
GY140-012	HYSTEROSCOPE, AUTOCLAVABLE 4,0 MM,12°,WL 302 MM	404935618026	36628	Rigid fibreoptic hysteroscope	7	IIa	TD-200	243
GY140-030	HYSTEROSCOPE, AUTOCLAVABLE 4,0 MM,30°,WL 302 MM	404935618027	36628	Rigid fibreoptic hysteroscope	7	IIa	TD-200	243
GY140-070	HYSTEROSCOPE, AUTOCLAVABLE 4,0 MM,70°,WL 302 MM	404935618028	36628	Rigid fibreoptic hysteroscope	7	IIa	TD-200	243
LP100-000	LAPAROSCOPE, AUTOCLAVABLE Ø 10.0 MM,0°,WL 340 MM, 4K READY	404935615854	12291	Rigid optical laparoscope	7	IIa	TD-200	243
LP100-030	LAPAROSCOPE, AUTOCLAVABLE Ø 10.0 MM,30°,WL 340 MM, 4K READY	404935615855	12291	Rigid optical laparoscope	7	IIa	TD-200	243
LP100-045	LAPAROSCOPE, AUTOCLAVABLE Ø 10,0 MM,45°,WL 340 MM, 4K READY	404935615856	12291	Rigid optical laparoscope	7	IIa	TD-200	243
LP105-000	LAPAROSCOPE, AUTOCLAVABLE Ø 10.0 MM,0°,WL 425 MM	404935615857	12291	Rigid optical laparoscope	7	IIa	TD-200	243
LP105-030	LAPAROSCOPE, AUTOCLAVABLE Ø 10.0 MM,30°,WL 425 MM	404935615858	12291	Rigid optical laparoscope	7	IIa	TD-200	243
LP105-045	LAPAROSCOPE, AUTOCLAVABLE Ø 10.0 MM,45°,WL 425 MM	404935615859	12291	Rigid optical laparoscope	7	IIa	TD-200	243
LP150-000	LAPAROSCOPE, AUTOCLAVABLE Ø 5.0 MM,0°,WL 300 MM, 4K READY	404935615860	12291	Rigid optical laparoscope	7	IIa	TD-200	243
LP150-030	LAPAROSCOPE, AUTOCLAVABLE Ø 5.0 MM,30°,WL 300 MM, 4K READY	404935615861	12291	Rigid optical laparoscope	7	IIa	TD-200	243
PS100-030	ENDO-PLASTIC ENDOSCOPE, Ø 10 MM,30°,WL 175MM	404935646949	12291	Rigid optical laparoscope	7	IIa	TD-200	243
PS105-030	ENDO-PLASTIC ENDOSCOPE, Ø 5 MM,30°,WL 175MM	404935646950	12291	Rigid optical laparoscope	7	IIa	TD-200	243
RZ010-000	PROTECTION SHIELD F.OPT.UP TO 5MM	404935627802	65703	Endoscope transport/sterilization protective cover, reusable	7	IIa	TD-200	243
RZ100-000	ENDOSCOPE ADAPTOR STORZ	404935627813	46113	Endoscopic light source adaptor	7	IIa	TD-200	243
RZ100-010	ENDOSCOPE-ADAPTOR WOLF	404935627814	46113	Endoscopic light source adaptor	7	IIa	TD-200	243
RZ200-202	SPARE PART PART VALVE HOLDER FOR AXIAL WORKING CHANNEL ON URS, SPARE PART FOR ALL URS	404935647918	37112	Rigid ureterorenoscope	7	IIa	TD-200	243
UR300-000	GUIDE ADAPTER F. LITHOTRIPSY HANDLE (LITHOCLAST)	404935627112	37112	Rigid ureterorenoscope	7	IIa	TD-200	462
UR300-050	SILICONE AUTOM. VALVE (DUCKBILL),Ø3,9MM, FOR URETERO-RENOSCOPE, (5 PCS./PACKAGE	404935625340	37112	Rigid ureterorenoscope	7	IIa	TD-200	243

1 Overview

TD No and Name	TD-200 endoscopes (arthroscope, hysteroscope, cystoscope, otoscope, sinuscope, uretero-renoscope, laparoscope)
Basic UDI-DI	4049356TD-200GY
Manufacturer	RUDOLF Medical GmbH + Co. KG Zollerstrasse 1 78567 Fridingen an der Donau, Germany www.rudolf-med.com sales@rudolf-med.com
EMDN No. and Term	Z12029009 LAPAROSCOPES

Name / No.	Description	Issue date
DIN EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes	2021-12
DIN EN ISO 14971	Medical devices - Application of risk management to medical devices	2022-04
DIN 96298-3	Medical instruments - Terms, measuring methods and tests - Part 3: Tests	2017-10
DIN EN 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices	2021-08
DIN EN 10088-1	Stainless steels - Part 1: List of stainless steels	2024-04
DIN EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2021-05
DIN EN ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	2009-10
DIN EN ISO 10993-10	Biological evaluation of medical devices - Part 10: Tests for skin sensitization	2023-04
ISO 10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	2017-09
DIN EN ISO 10993-12	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	2021-08
DIN EN ISO 10993-18	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process	2023-11
DIN EN ISO 10993-23	Biological evaluation of medical devices - Part 23: Tests for irritation	2021-10
DIN EN ISO 11737-1	Sterilization of health care products - Microbiological methods – Part 1: Determination of a population of microorganisms on products	2021-10

Name / No.	Description	Issue date
DIN EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	2022-02
DIN EN ISO 17664-1	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices	2021-11
DIN EN ISO 17664-2	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices	2024-04
DIN EN ISO 17665	Sterilization of health care products - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices	2024-09
DIN EN ISO 20417	Medical devices – Information to be supplied by manufacturer	2022-03
DIN EN ISO 7153-1	Surgical instruments - Materials - Part 1: Metals	2017-02
MDCG 2018-1 rev. 4	MDCG 2018-1 Rev.4 Guidance on BASIC UDI-DI and changes to UDI-DI	April 2021
MDCG 2019-15 rev. 1	Guidance notes for manufacturers of class I medical devices	Dec. 2019
MDCG 2019-5	Registration of legacy devices in EUDAMED	April 2019
MDCG 2020-5	Clinical Evaluation - Equivalence A guide for manufacturers and notified bodies	April 2020
MDCG 2020-6	Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC	April 2020
MDCG 2020-8	Guidance on PMCF evaluation report template	April 2020
MDCG 2020-7	Guidance on PMCF plan template	April 2020
MDCG 2021-19	Guidance note integration of the UDI within an organisation's quality management system	July 2021
MDCG 2021-24	Guidance on classification of medical devices	Oct. 2021
MDCG 2021-25 Rev. 1	Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC	Oct. 2024
MDCG 2022-21	Guidance on periodic safety update report (PSUR) according to regulation (EU) 2017/745 (MDR)	Dec. 2022
MDCG 2023-3	Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices	Feb. 2023
MEDDEV 2.7.1 Rev	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Rev 4	2016-07
Directive 2011/65/EU	RoHS	2011
ISO 8600-1	Endotherapy devices. Eyepiece cap and light guide connector	2015-10

Name / No.	Description	Issue date
ISO 8600-3	Endoscopes - Medical endoscopes and endotherapy devices – Part 3: Determination of field of view and direction of view of endoscopes with optics	2019-08
ISO 8600-4	Endoscopes - Medical endoscopes and endotherapy devices – Part 4: Determination of maximum width of insertion portion	2014-03
ISO/TS 18339	Endotherapy devices. Eyepiece cap and light guide connector	2015-11
DIN EN 60601-2-18	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment	2016-10

2 Document History

Revision	Date (YYYY.MM.DD)	Author	Description
A	01.04.2025	Ayfer Bektas	Moving the product standards and guidances into this separate document. The list is no longer embedded in the corresponding documents but attached to them.