

Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.: SX 1494760-1

Certificate Holder: Kliniken Nordoberpfalz AG
Söllnerstr. 16
92637 Weiden
Germany

Scope: Reprocessing of medical devices including class "critical C" in the Reprocessing Units for Medical Devices (RUMED) according to the Recommendation of the Commission for Hospital Hygiene and Infectious Disease Prevention (KRINKO) at the Robert-Koch-Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) concerning the "Hygiene Requirements for Reprocessing of Medical Devices"

Medical devices classification "critical C":

Olympus Medical Systems Corp.
- flexible Bronchoscope, article no.: BF1T180, BF1T60, BFP60, BFQ180, BFTE2, BF-UC190F, BF-H190, BF-1TH190
- Rhino-Laryngo-Videoscope, article no.: ENF-VQ
- Tracheal-Intubation-Fiberscope, article no.: LF-GP, LF-TP
- Cysto-Nephro-Fiberscope, article no.: CYF-5
- Uretero-Reno-Fiberscope, article no.: URF-V3, URF-P7

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 1164699-10

Effective date: 2024-11-28

Expiry date: 2026-07-03

Issue date: 2024-11-28

Replaces certificate SX 1494760-1 issued 16.06.2023

This certificate can be validated on <https://www.certipedia.com>



Mareike Kraus
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

© TÜV, TÜEV and TÜV are registered trademarks. Utilisation and application requires prior approval.

Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.: SX 1494760-1

Certificate Holder: Kliniken Nordoberpfalz AG
Söllnerstr. 16
92637 Weiden
Germany

Intuitiv Surgical Inc.

- daVinci Xi 8 mm Endoscope 30°, article no.: 470027
- daVinci Xi 8 mm Endoscope 0°, article no.: 470026
- daVinci Xi 8 mm Endoskop plus 0°, article no.: 470056
- daVinci Xi 8 mm Endoskop plus 30°, article no.: 470057

Richard Wolf GmbH

- Video-Uretero-Cystoscope, article no.: 731000.144
- Cysto-Uretero-Fiberskop, article no.: 7305.001
- Sensor Cystoscope Vision, article no.: 7315001, 7315006
- Sensor Cystoscope Vision EF, article no.: 73151001, 73151006
- Cysto-Uretero-Fiberscope (Viper), article no.: 7325.071
- Uretero-Reno-Fiberscope, article no.: 7325.172
- Choledochoscope, article no.: 7325.152
- Cysto-Uretero-Fiberscope (Cobra), article no.: 7326071
- Cysto-Uretero-Fiberscope (Cobra), article no.: 7326076
- Choledocho-Fiberscope, article no.: 7330.052
- Fiber-Uretero-Renoscope, article no.: 7330.072
- Uretero-Reno-Fiberscope (Boa Vision), article no.: 7355071
- Uretero-Reno-Fiberscope (Boa Vision), article no.: 7355076
- Uretero-Reno-Fiberscope (Cobra Vision), article no.: 7356071
- Uretero-Reno-Fiberscope (Cobra Vision), article no.: 7356076
- Sensor-Ureterorenoscopy, article no.: 73561076

This certificate can be validated on <https://www.certipedia.com>

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 1494760-1

Certificate Holder: Kliniken Nordoberpfalz AG
Söllnerstr. 16
92637 Weiden
Germany

Karl Storz SE & Co. KG

- Broncho-Fiberscope, article no.: 11001BN1, 11002BD1, 11003BC3, 11005BC1
- Rhino-Laryngo-Fiberscope, article no.: 11101RP2
- Cysto-Uretero-Fiberscope, article no.: 11272C1, 11274AA1, 11272VP, 11272VH
- Uretero-Fiberscope FLEX-X², article no.: 11278 A1
- Choledocho-Fiberscope, article no.: 11292AD1, 11292DE1
- Intubation-Fiberscope, article no.: 11301AA1, 11301BN1, 11302BD2, 11303BD1
- Intubation-Videoendoscope, article no.: 11303BNX
- Uretero-Reno-Fiberscope FLEX-XC, article no.: 11278VS

Myelotec, Inc.

- flexible Fiberendoscope, article no.: 3000 E

This certificate can be validated on <https://www.certipedia.com>

Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.: SX 1494760-1
Certificate Holder: Kliniken Nordoberpfalz AG
Söllnerstr. 16
92637 Weiden
Germany

The scope of certification covers the following sites:

No.	Facility	Scope
/01	c/o Kliniken Nordoberpfalz AG Söllnerstr. 16 92637 Weiden Germany	Management
/02	c/o Klinikum Weiden AEMP Söllnerstr. 16 92637 Weiden Germany	Reprocessing of medical devices including class "critical C", incl. cleaning, disinfection, sterilization
/03	c/o Krankenhaus Kemnath AEMP Werner-von-Siemens-Str. 7 95478 Kemnath Germany	Reprocessing of medical devices including class "critical B", incl. cleaning, disinfection, sterilization

This certificate can be validated on <https://www.certipedia.com>