



CERTIFICATE



This is to certify that

KARL STORZ SE & Co. KG

Dr.-Karl-Storz-Straße 34
78532 Tuttlingen
Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope:

Sales and marketing of active medical and veterinary devices, non-active medical and veterinary devices, implants and sterile medical devices, and technical imaging and video systems.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 9001 : 2015

Certificate registration no.	528525 QM15
Certificate unique ID	170776315
Effective date	2021-09-12
Expiry date	2024-09-11
Frankfurt am Main	2021-07-26



DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de



Annex to certificate
Certificate registration No.: 528525 QM15
Certificate unique ID: 170776315
Effective date: 2021-09-12

KARL STORZ SE & Co. KG

Dr.-Karl-Storz-Straße 34
78532 Tuttlingen
Germany

Location

Scope

537711
KARL STORZ SE & Co. KG
Dr.-Karl-Storz-Straße 34
78532 Tuttlingen
Germany

Sales and marketing of active medical and veterinary devices, non-active medical and veterinary devices, implants and sterile medical devices, and technical imaging and video systems.

549394
KARL STORZ SE & Co. KG
take-off Gewerbepark 83
78579 Neuhausen ob Eck
Germany

Distribution of active medical and veterinary devices, non-active medical and veterinary devices, implants and sterile medical devices, and technical imaging and video systems.



CERTIFICATE

No. QS6 084462 0044 Rev. 04

Certificate Holder: **KARL STORZ SE & Co. KG**
Dr.-Karl-Storz-Straße 34
78532 Tuttlingen
GERMANY

Certification Mark:



Scope of Certificate: **See Pages 2-4 for Overall Scope Statement.**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, Japan MHLW / PMDA, USA FDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:QS6_084462_0044_Rev_04

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F001257**
Report No.: **713280356**
Effective Date: **2023-06-29**
Expiry Date: **2025-05-09**

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Regulatory Requirements: Audit/Certification Criteria

Australia

- Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil

- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

Canada

- Medical Device Regulations – Part 1- SOR 98/282

Japan

- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
- Japan PMD Act (as applicable)

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820
- 21 CFR Part 821

Overall Scope Statement:

Design and Development, Production and Distribution of Active and Non-Active Medical Devices:

- Equipment Carts
- Fiberscopes and Semiflexible Endoscopes (Fiberscopes with and without Channel, Semiflexible Endoscopes with and without Channel)
- HF Systems (HF Instruments with Movable Jaws / HF Instruments without Movable Jaws / HF Electrodes (Sterile / Non-Sterile), HF Suction / Irrigation Instruments, HF Cables, HF Generators, HF Foot Switches, HF Working Elements)
- Optics (Rigid Endoscopes with and without Channel)
- Hygiene / Cleaning (Sterilization Trays / Perforated Baskets)
- Illumination Systems (Light Sources, Light Cables, Light Carrier, Head Lamps, Battery Light Sources)

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- Imaging Systems (Camera Heads, CCUs, Monitors, Exoscopes)
- Implants (Non-Active Implants for ENT (Sterile), Non-Active Bone Implants for Arthroscopic Procedures (Sterile), Bioabsorbable Implants for Arthroscopic Procedures (Sterile), Surgical Suture Material for Arthroscopic Procedures (Sterile))
- Instruments (Instruments with Movable Jaws / Instruments without Movable Jaws (Sterile / Non-Sterile), Working Elements / Working Inserts, Suction / Irrigation Instruments (Sterile / Non-Sterile))
- Catheters (Sterile / Non-Sterile)
- Cannulas (Sterile / Non-Sterile)
- Sheaths, Trocars (Sterile / Non-Sterile)
- Insufflators, Tubing Sets (Sterile / Non-Sterile)
- Laser (Laser Devices, Foot Switch for Laser, Laser Fibers (Sterile / Non-Sterile), Lithotriptors (Lithotripsy Devices, Foot Switches Lithotripsy Devices, Lithotripsy Probes (Sterile / Non-Sterile))
- Morcellator Systems and Accessories for Endoscopic Therapy
- Motors (Motor Control Unit, Handpieces Motors, Foot Switches for Motor Control Unit, Shaver / Drills (Sterile / Non-Sterile))
- Navigation (Navigation Units, EM Navigation)
- Data Storage, Data Management and Routing Systems, Active Controlling Systems, Components of Software
- Pumps (Pumps, Foot Switches for Pumps, Tubing Sets (Sterile / Non-Sterile))
- Retaining Systems
- Videoendoscopes (Rigid Videoscopes with and without Channel, Flexible Videoscopes with and without Channel (Sterile / Non-Sterile))

Installation of Active Medical Devices:

- Data Storage, Data Management and Routing Systems, Active Controlling Systems, Components of Software

Servicing of Active and Non-Active Medical Devices:

- Equipment Carts

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- Fiberscopes and Semiflexible Endoscopes (Fiberscopes with and without Channel, Semiflexible Endoscopes with and without Channel)
- HF Systems (HF Instruments with Movable Jaws / HF Instruments without Movable Jaws / HF Electrodes, HF Suction / Irrigation Instruments, HF Cables, HF Generators, HF Foot Switches, HF Working Elements)
- Optics (Rigid Endoscopes with and without Channel)
- Illumination Systems (Light Sources, Light Cables, Light Carrier, Head Lamps, Battery Light Sources)
- Imaging Systems (Camera Heads, CCUs, Monitors, Exoscopes)
- Instruments (Instruments with Movable Jaws / Instruments without Movable Jaws, Working Elements / Working Inserts, (Suction / Irrigation Instruments)
- Catheters
- Cannulas
- Sheaths, Trocars
- Insufflators / Tubing Sets
- Laser (Laser Devices, Foot Switch for Laser, Laser Fibers)
- Lithotriptors (Lithotripsy Devices, Foot Switches Lithotripsy Devices, Lithotripsy Probes)
- Morcellator Systems and Accessories for Endoscopic Therapy
- Motors (Motor Control Unit, Handpieces / Motors, Foot Switches for Motor Control Unit, Shaver / Drills)
- Navigation (Navigation Units, EM Navigation)
- Data Storage, Data Management and Routing Systems, Active Controlling Systems, Components of Software
- Pumps (Pumps, Foot Switches for Pumps, Tubing Sets)
- Retaining Systems
- Videoendoscopes (Rigid Videoscopes with and without Channel, Flexible Videoscopes with and without Channel)

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No. QS6 084462 0044 Rev. 04

Facility(ies):

KARL STORZ SE & Co. KG

Dr.-Karl-Storz-Straße 34, 78532 Tuttlingen, GERMANY

KARL STORZ SE & Co. KG

Dr.-Karl-Storz-Straße 11, 78532 Tuttlingen, GERMANY

KARL STORZ SE & Co. KG

Elsa-Brandström-Weg 11 & 21, 78532 Tuttlingen, GERMANY

KARL STORZ SE & Co. KG

Kaiserstraße 10, 78532 Tuttlingen, GERMANY

KARL STORZ SE & Co. KG

take-off Gewerbepark 83, 78579 Neuhausen ob Eck, GERMANY

KARL STORZ SE & Co. KG

take-off Gewerbepark 44-47, 78579 Neuhausen ob Eck, GERMANY

Storz Endoskop Produktions GmbH

Schneckenackerstr. 1, 8200 Schaffhausen, SWITZERLAND

KARL STORZ SE & Co. KG

Scharnhorststraße 3, 10115 Berlin, GERMANY

KARL STORZ SE & Co. KG

Friedrich-List-Straße 6, 76297 Stutensee, GERMANY

KARL STORZ SE & Co. KG

Unter Buchsteig 8, 78532 Tuttlingen-Möhringen, GERMANY

KARL STORZ Video Endoscopy Estonia OÜ

Pärnu maantee 556b, Laagri, 76401 Harju maakond, ESTONIA

Storz Endoskop Produktions GmbH

Ernst-Müller Strasse 8, 8200 Schaffhausen, SWITZERLAND

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Facility Scopes:

KARL STORZ SE & Co. KG

Dr.-Karl-Storz-Straße 34, 78532 Tuttlingen, GERMANY

Design and Development of Active Medical Devices:

- Data Storage, Data Management and Routing Systems, Active Controlling Systems, Components of Software

Distribution of Active and Non-Active Medical Devices:

- Optics (Rigid Endoscopes with and without Channel)
- Fiberscopes and Semiflexible Endoscopes (Fiberscopes with and without Channel, Semiflexible Endoscopes with and without Channel)
- Videoendoscopes (Rigid Videoscopes with and without Channel, Flexible Videoscopes with and without Channel (Sterile / Non-Sterile))
- Retaining Systems
- Equipment Carts
- Imaging Systems (Camera Heads, CCUs, Monitors, Exoscopes)
- Lithotriptors (Lithotripsy Devices, Foot Switches Lithotripsy Devices, Lithotripsy Probes (Sterile / Non-Sterile))
- Pumps (Pumps, Foot Switches for Pumps, Tubing Sets (Sterile / Non-Sterile))
- HF Systems (HF Instruments with Movable Jaws / HF Instruments without Movable Jaws / HF Electrodes (Sterile / Non-Sterile), HF Suction / Irrigation Instruments, HF Cables, HF Generators, HF Foot Switches, HF Working Elements)
- Laser (Laser Devices, Foot Switch for Laser, Laser Fibers (Sterile / Non-Sterile))
- Motors (Motor Control Unit, Handpieces / Motors, Foot Switches for Motor Control Unit, Shaver / Drills (Sterile / Non-Sterile))
- Morcellator Systems and Accessories for Endoscopic Therapy
- Data Storage, Data Management and Routing Systems, Active Controlling Systems, Components of Software
- Illumination Systems (Light Sources, Light Cables, Light Carrier, Head Lamps, Battery Light Sources)
- Insufflators, Tubing Sets (Sterile / Non-Sterile)

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- Instruments (Instruments with Movable Jaws / Instruments without Movable Jaws (Sterile / Non-Sterile), Working Elements / Working Inserts, (Suction / Irrigation Instruments (Sterile / Non-Sterile))
- Catheters (Sterile / Non-Sterile)
- Cannulas (Sterile / Non-Sterile)
- Sheaths, Trocars (Sterile / Non Sterile)
- Navigation (Navigation Units, EM Navigation)
- Hygiene / Cleaning (Sterilization Trays / Perforated Baskets)
- Implants (Non-Active Implants for ENT (Sterile), Non-Active Bone Implants for Arthroscopic Procedures (Sterile), Bioabsorbable Implants for Arthroscopic Procedures (Sterile), Surgical Suture Material for Arthroscopic Procedures (Sterile))

Servicing Regarding Customer Support of Reusable Active and Non-Active Medical Devices:

- Optics (Rigid Endoscopes with and without Channel)
- Fiberscopes and Semiflexible Endoscopes (Fiberscopes with and without Channel, Semiflexible Endoscopes with and without Channel)
- Videoendoscopes (Rigid Videoscopes with and without Channel, Flexible Videoscopes with and without Channel)
- Retaining Systems
- Equipment Carts
- Imaging Systems (Camera Heads, CCUs, Monitors, Exoscopes)
- Lithotripsy (Lithotripsy Devices, Foot Switches Lithotripsy Devices, Lithotripsy Probes)
- Pumps (Pumps, Foot Switches for Pumps, Tubing Sets)
- HF Systems (HF Instruments with Movable Jaws, HF Instruments without Movable Jaws / HF Electrodes, HF Suction / Irrigation Instruments, HF Cables, HF Generators, HF Foot Switches, HF Working Elements)
- Laser (Laser Devices, Foot Switches for Laser, Laser Fibers)
- Motors (Motor Control Unit, Handpieces / Motors, Foot Switches for Motor Control Unit, Shaver / Drills)
- Morcellator Systems and Accessories for Endoscopic Therapy, Data Storage, Data Management and Routing Systems, Active Controlling Systems, Components of Software

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- Illumination Systems (Light Sources, Light Cables, Light Carrier, Head Lamps, Battery Light Sources)
- Insufflators / Tubing Sets
- Instruments (Instruments with Movable Jaws, Instruments without Movable Jaws, Working Elements / Working Inserts (Suction / Irrigation Instruments))
- Catheters
- Cannulas
- Sheaths, Trocars
- Navigation (Navigation Units, EM Navigation)

REPs Facility ID: F001257

KARL STORZ SE & Co. KG

Dr.-Karl-Storz-Straße 11, 78532 Tuttlingen, GERMANY

Design and Development of Active and Non-Active Medical Devices:

- Instruments (Instruments with Movable Jaws / Instruments without Movable Jaws (Sterile / Non-Sterile), Working Elements / Working Inserts, (Suction / Irrigation Instruments (Sterile / Non-Sterile))
- Catheters (Sterile / Non-Sterile)
- Cannulas (Sterile / Non-Sterile)
- Sheaths and Trocars (Sterile / Non-Sterile)
- Implants (Non-Active Implants for ENT (Sterile), Non-Active Bone Implants for Arthroscopic Procedures (Sterile), Bioabsorbable Implants for Arthroscopic Procedures (Sterile), Surgical Suture Material for Arthroscopic Procedures (Sterile))
- Optics (Rigid Endoscopes with and without Channel)
- Fiberscopes and Semiflexible Endoscopes (Fiberscopes with and without Channel, Semiflexible Endoscopes with and without Channel)
- Videoendoscopes (Rigid Videoscopes with and without Channel, Flexible Videoscopes with and without Channel (Sterile / Non-Sterile))
- Retaining Systems
- Equipment Carts
- Lithotriptors (Lithotripsy Probes (Sterile / Non-Sterile))

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- HF Systems (HF Instruments with Movable Jaws / HF Instruments without Movable Jaws / HF Electrodes (Sterile / Non-Sterile), HF Suction / Irrigation Instruments, HF Working Elements)
- Hygiene / Cleaning (Sterilization Trays / Perforated Baskets)
- Imaging Systems (Exoscopes)

Production of Active and Non-Active Medical Devices:

- Instruments (Instruments with Movable Jaws/Instruments without Movable Jaws (Sterile/Non-Sterile), Working Elements/Working Inserts, (Suction/Irrigation Instruments)
- Catheters
- Cannulas
- Sheaths and Trocars
- Optics (Rigid Endoscopes with and without Channel)
- Fiberscopes and Semiflexible Endoscopes (Fiberscopes with and without Channel, Semiflexible Endoscopes with and without Channel)
- Videoendoscopes (Rigid Videoscopes with and without Channel)
- HF Systems (HF Instruments with Movable Jaws/HF Instruments without Movable Jaws/HF Electrodes (Sterile/Non-Sterile), HF Suction/Irrigation Instruments, HF Working Elements)
- Hygiene/Cleaning (Sterilization Trays/Perforated Baskets)
- Imaging Systems (Exoscopes)
- Illumination Systems (Light Cables, Light Carrier, Head Lamps, Components for Illumination Systems)

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KARL STORZ SE & Co. KG

Elsa-Brandström-Weg 11 & 21, 78532 Tuttlingen, GERMANY

Production of Active and Non-Active Medical Devices:

- Instruments (Instruments with Movable Jaws / Instruments without Movable Jaws (Sterile / Non-Sterile), Working Elements / Working Inserts, (Suction / Irrigation Instruments)
- Catheters
- Cannulas

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- HF Systems (HF Instruments with Movable Jaws / HF Instruments without Movable Jaws / HF Electrodes, HF Suction / Irrigation Instruments, HF Working Elements)
- Sheaths, Trocars
- Lithotriptors (Lithotripsy Probes)
- Illumination Systems (Head Lamps, Components for Illumination Systems)
- Imaging Systems (Components for Imaging Systems)
- Optics (Components for Optics)
- Retaining Systems (Components for Retaining Systems)
- Pumps (Components for Pump Sets)
- Hygiene/Cleaning (Components for Hygiene/Cleaning)

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KARL STORZ SE & Co. KG

Kaiserstraße 10, 78532 Tuttlingen, GERMANY

Production of Active Medical Devices:

- Data Storage, Data Management and Routing Systems, Active Controlling Systems
- Lithotriptors (Foot Switches for Lithotripsy Devices)
- Illumination Systems (Light Sources)
- Retaining Systems
- HF Systems (HF Foot Switches)
- Motors (Foot Switches Motor Control Unit)
- Laser (Foot Switch Laser)
- Imaging Systems (CCUs)
- Pumps (Pumps, Foot Switches Pumps, Tubing Sets non-sterile)
- Navigation (Components for Navigation)

Servicing Regarding Maintenance of Reusable Active Medical Devices:

- Laser (Laser Devices, Foot Switches for Laser Devices)

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KARL STORZ SE & Co. KG

take-off Gewerbepark 83, 78579 Neuhausen ob Eck, GERMANY

Central Functions related to the Quality Management System

Distribution of Active and Non-Active Medical Devices:

- Implants (Non-Active Implants for ENT (Sterile), Non-Active Bone Implants for Arthroscopic Procedures (Sterile), Bioabsorbable Implants for Arthroscopic Procedures (Sterile), Surgical Suture Material for Arthroscopic Procedures (Sterile))
- Optics (Rigid Endoscopes with and without Channel)
- Fiberscopes and Semiflexible Endoscopes (Fiberscopes with and without Channel, Semiflexible Endoscopes with and without Channel)
- Videoendoscopes (Rigid Videoscopes with and without Channel, Flexible Videoscopes with and without Channel (Sterile / Non-Sterile))
- Retaining Systems
- Equipment Carts
- Imaging Systems (Camera Heads, CCUs, Monitors, Exoscopes)
- Lithotripsy (Lithotripsy Devices, Foot Switches for Lithotripsy Devices, Lithotripsy Probes (Sterile / Non-Sterile))
- Pumps (Pumps, Foot Switches for Pumps, Tubing Sets (Sterile / Non-Sterile))
- HF Systems (HF Instruments with Movable Jaws / HF Instruments without Movable Jaws / HF Electrodes (Sterile / Non-Sterile), HF Suction / Irrigation Instruments, HF Cables, HF Generators, HF Foot Switches, HF Working Elements)
- Laser (Laser Devices, Foot Switches for Laser, Laser Fibers (Sterile / Non-Sterile))
- Motors (Motor Control Unit, Handpieces / Motors, Foot Switches for Motor Control Unit, Shaver / Drills (Sterile / Non-Sterile))
- Morcellator Systems and Accessories for Endoscopic Therapy
- Data Storage, Data Management and Routing Systems, Active Controlling Systems, Components of Software
- Illumination Systems (Light Sources, Light Cables, Light Carrier, Head Lamps, Battery Light Sources)
- Insufflators, Tubing Sets (Sterile / Non-Sterile)

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- Instruments (Instruments with Movable Jaws / Instruments without Movable Jaws (Sterile / Non-Sterile), Working Elements / Working Inserts, (Suction / Irrigation Instruments (Sterile / Non-Sterile))
- Catheters (Sterile / Non-Sterile)
- Cannulas (Sterile / Non-Sterile)
- Sheaths, Trocars (Sterile / Non-Sterile)
- Navigation (Navigation Units, EM Navigation)
- Hygiene / Cleaning (Sterilization Trays / Perforated Baskets)

Servicing Regarding Maintenance of Reusable Active and Non-Active Medical Devices:

- Optics (Rigid Endoscopes with and without Channel)
- Fiberscopes and Semiflexible Endoscopes (Fiberscopes with and without Channel, Semiflexible Endoscopes with and without Channel)
- Videoendoscopes (Rigid Videoscopes with and without Channel, Flexible Videoscopes with and without Channel)
- Retaining Systems
- Equipment Carts
- Imaging Systems (Camera Heads, CCUs, Monitors, Exoscopes)
- Lithotriptors (Lithotripsy Devices, Foot Switches for Lithotripsy Devices, Lithotripsy Probes)
- Pumps (Pumps, Foot Switches for Pumps, Tubing Sets)
- HF Systems (HF Instruments with Movable Jaws, HF Instruments without Movable Jaws / HF Electrodes, HF Suction / Irrigation Instruments, HF Cables, HF Generators, HF Foot Switches, HF Working Elements)
- Laser (Laser Devices, Foot Switches for Laser, Laser Fibers)
- Motors (Motor Control Unit, Handpieces / Motors, Foot Switches for Motor Control Unit, Shaver / Drills)
- Morcellator Systems and Accessories for Endoscopic Therapy
- Data Storage, Data Management and Routing Systems, Active Controlling Systems, Components of Software
- Illumination Systems (Light Sources, Light Cables, Light Carrier, Head Lamps, Battery Light Sources)
- Insufflators / Tubing Sets
- Instruments (Instruments with Movable Jaws, Instruments without Movable Jaws, Working Elements / Working Inserts, (Suction / Irrigation Instruments)

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- Catheters
- Cannulas
- Sheaths, Trocars
- Navigation (Navigation Units, EM Navigation)

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KARL STORZ SE & Co. KG

take-off Gewerbepark 44-47, 78579 Neuhausen ob Eck, GERMANY

Production (Metal Processing of Components for Active and Non-Active Medical Devices)

Final Cleaning and Non-Sterile Final Packaging of:

- Instruments (Instruments with Movable Jaws / Instruments without Movable Jaws (Sterile / Non-Sterile), Working Elements / Working Inserts (Suction / Irrigation Instruments)
- Catheters
- Cannulas
- Optics (Rigid Endoscopes with and without Channel)
- Imaging Systems (Exoscopes)
- HF Systems (HF Instruments with Movable Jaws / HF Instruments without Movable Jaws / HF Electrodes (Sterile / Non-Sterile), HF Suction / Irrigation Instruments, HF Working Elements)
- Sheath, Trocars
- Illumination Systems (Light Cables, Light Carrier, Head Lamps)
- Fiberscopes and Semiflexible Endoscopes (Fiberscopes with and without Channel, Semiflexible Endoscopes with and without Channel)
- Videoendoscopes (Rigid Videoscopes with and without Channel)

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Storz Endoskop Produktions GmbH

Schneckenackerstr. 1, 8200 Schaffhausen, SWITZERLAND

Design and Development of Active and Non-Active Medical Devices:

- Retaining Systems
- Equipment Carts
- Insufflators, Tubing Sets (Sterile / Non-Sterile)
- Fiberscopes and Semiflexible Endoscopes (Fiberscopes with and without Channel, Semiflexible Endoscopes with and without Channel)
- Videoendoscopes (Rigid Videoscopes with and without Channel, Flexible Videoscopes with and without Channel)
- Lithotriptors (Lithotripsy Devices, Foot Switches Lithotripsy Devices)
- HF Systems (HF Cables, HF Generators, HF Foot Switches)
- Pumps (Pumps, Foot Switches for Pumps, Tubing Sets (Sterile / Non-Sterile))
- Motors (Motor Control Unit, Handpieces / Motors, Foot Switches for Motor Control Unit, Shaver / Drills)
- Morcellator Systems and Accessories for Endoscopic Therapy
- Illumination Systems (Light Sources, Light Cables, Light Carrier, Head Lamps, Battery Light Sources)
- Navigation (Navigation Units, EM Navigation)

Production of Active and Non-Active Medical Devices:

- Optics (Rigid Endoscopes with and without Channel)
- Imaging Systems (Exoscopes)
- Components of Fiberscopes and Semiflexible Endoscopes (Fiberscopes with and without Channel, Semiflexible Endoscopes with and without Channel)
- Components of Videoendoscopes (Rigid Videoscopes with and without Channel, Flexible Videoscopes with and without Channel)
- Pumps (Pumps, Foot Switches Pumps, Tubing Sets)
- Insufflators, Tubing Sets
- Illumination Systems (Light Sources)
- Motors (Motor Control Unit, Foot Switches Motor Control Unit)

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KARL STORZ SE & Co. KG

Scharnhorststraße 3, 10115 Berlin, GERMANY

Design and Development of Active Medical Devices

- Retaining Systems
- Data Storage, Data Management and Routing Systems, Active Controlling Systems, Components of Software

REPs Facility ID: F002171

KARL STORZ SE & Co. KG

Friedrich-List-Straße 6, 76297 Stutensee, GERMANY

Production and Installation of Active Medical Devices:

- Data Storage, Data Management and Routing Systems, Active Controlling Systems, Components of Software

Servicing Regarding Maintenance of Reusable Active Medical Devices:

- Data Storage, Data Management and Routing Systems, Active Controlling Systems, Components of Software

Distribution of Active Medical Devices:

- Data Storage, Data Management and Routing Systems, Active Controlling Systems, Components of Software

REPs Facility ID: F002170

KARL STORZ SE & Co. KG

Unter Buchsteig 8, 78532 Tuttlingen-Möhringen, GERMANY

Design and Development of Active Medical Devices:

- Data Storage, Data Management and Routing Systems, Active Controlling Systems

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- Lithotriptors (Lithotripsy Devices, Foot Switches for Lithotripsy Devices)
- Illumination Systems (Light Sources, Light Cables, Light Carrier, Head Lamps, Battery Light Sources)
- Imaging Systems (CCUs)

REPs Facility ID: F001257

KARL STORZ Video Endoscopy Estonia OÜ

Pärnu maantee 556b, Laagri, 76401 Harju maakond, ESTONIA

Design and Development of Active and Non-Active Medical Devices:

- Videoendoscopes (Rigid Videoscopes with and without Channel, Flexible Videoscopes with and without Channel)
- Fiberscopes and Semiflexible Endoscopes (Fiberscopes with and without Channel; Semiflexible Endoscopes with and without Channel)
- Components of Videoendoscopes

Production of Active and Non-Active Medical Devices:

- Videoendoscopes (Rigid Videoscopes with and without Channel, Flexible Videoscopes with and without Channel (Sterile / Non-Sterile))
- Fiberscopes and Semiflexible Endoscopes (Fiberscopes with and without Channel; Semiflexible Endoscopes with and without Channel)
- Components of Videoendoscopes (Sterile / Non-Sterile)

Servicing Regarding Maintenance of Reusable Active and Non-Active Medical Devices:

- Videoendoscopes (Rigid Videoscopes with and without Channel, Flexible Videoscopes with and without Channel)
- Fiberscopes and Semiflexible Endoscopes (Fiberscopes with and without Channel; Semiflexible Endoscopes with and without Channel)

REPs Facility ID: F002169

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Date of Issue: 2023-07-21

(Renee Walker)
Director, US Certification Body, MHS



CERTIFICATE

No. QS6 084462 0044 Rev. 04

Storz Endoskop Produktions GmbH

Ernst-Müller Strasse 8, 8200 Schaffhausen, SWITZERLAND

Servicing Regarding Maintenance of Reusable Active and Non-Active Medical Devices:

- Imaging Systems (Camera Heads, CCUs, Monitors)
- Pumps (Pumps, Foot Switches Pumps)
- Insufflators
- Illumination Systems (Light Sources)
- Data Storage, Data Management and Routing Systems, Active controlling Systems
- Retaining Systems
- HF Systems (Generators, HF Foot Switches)
- Motors (Motor Control Unit, Foot Switches for Motor Control Unit)
- Lithotriptors (Lithotripsy Devices, Foot Switches for Lithotripsy Devices)
- Laser (Foot Switch Laser)

REPs Facility ID: F001257

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Date of Issue: 2023-07-21

(Renee Walker)
Director, US Certification Body, MHS



EC-DECLARATION OF CONFORMITY

EG-KONFORMITÄTSERKLÄRUNG

Device Name Produkt Name	Bronchoscope, size 3
Model Number(s) Modell Nummer(n)	10339EE
Classification Klassifizierung	Class IIa per Annex IX, Rule 6 of Council Directive 93/42/EEC Klasse IIa gemäß Anhang IX, Regel 6 der Richtlinie 93/42/EWG des Rates

We issue the present Declaration of Conformity on our sole responsibility and herewith declare self-dependent that the device mentioned above meets the Essential Requirements as defined in Annex I MDD 93/42/EEC .
Wir stellen die vorliegende Konformitätserklärung in Eigenverantwortung aus und erklären hiermit unter alleiniger Verantwortung, dass das oben genannte Produkt die Grundlegenden Anforderungen gemäß Anhang I MDD 93/42/EWG erfüllt.

This Declaration of Conformity is issued according to Annex II excluding (4) Council Directive 93/42/EEC for Medical Devices (for class IIa and IIb devices).

Diese Konformitätserklärung ist erstellt gemäß Anhang II ohne Abschnitt (4) Richtlinie 93/42/EWG des Rates über Medizinprodukte (für Klasse IIa und IIb Produkte).

Notified Body / Registration Number / Benannte Stelle / Registrierungsnummer:
TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München / 0123

Full list of applied standards, directives and laws (12-C2.3.F013-LOAS-CM001) on request.
Vollständige Liste angewandter Normen, Richtlinien und Gesetze (12-C2.3.F013-LOAS-CM001) auf Anfrage.

The validity of this declaration is determined by EC certificate number: G1 18 04 84462 012
Die Gültigkeit dieser Erklärung bestimmt sich nach dem EG Zertifikat mit der Nummer: G1 18 04 84462 012

CE0123

KARL STORZ SE & Co. KG
Dr.-Karl-Storz-Straße 34
78532 Tuttlingen
Germany

Tuttlingen, 17 Juli 2018


i. V. Serkan Sezer
Vice President
Global Quality Management,
Regulatory Affairs, RSB & Service



*This declaration loses all validity if KARL STORZ SE & Co. KG performs a product change which affects the Conformance to the Essential Requirements or an alteration of any kind not approved by KARL STORZ SE & Co. KG was made at the device mentioned above.
Diese Erklärung verliert ihre Gültigkeit sobald KARL STORZ SE & Co. KG Produktänderungen durchführt, welche die Konformität mit den Grundlegenden Anforderungen beeinflusst oder eine Änderung jeglicher Art ohne Freigabe durch die KARL STORZ SE & Co. KG am oben genannten Produkt durchgeführt wird.*

STORZ

KARL STORZ — ENDOSKOPE

EU-Declaration of Conformity

EU-Konformitätserklärung

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.
Diese Europäische Konformitätserklärung wird in alleiniger Verantwortung des Herstellers ausgestellt.

**MANUFACTURER
HERSTELLER**

Name of Company <i>Firmen Name</i>	Address <i>Adresse</i>	SRN <i>SRN</i>
KARL STORZ SE & Co. KG	Dr.-Karl-Storz-Str. 34 78532 Tuttlingen Germany	DE-MF-000005723

**PRODUCT IDENTIFICATION
PRODUKTIDENTIFIZIERUNG**

Device Description <i>Produkt Bezeichnung</i>	Basic UDI-DI <i>Basis UDI-DI</i>
Prismatic Light Deflector	4048551000082T8

**Intended use
Zweckbestimmung**

Prismatic light deflectors are used for proximal illumination in rigid bronchoscopes, tracheoscopes, and esophagoscopes. Prismatic light deflectors are non-invasive and are designed for transient use in invasive procedures through a body orifice.

**REF Number(s), Short text
REF Nummer(n), Kurztext**

10101HA Prismatic Light Deflector, 10101FA Prismatic Light Deflector

**RISK CLASS (according Annex VIII (EU) 2017/745)
RISIKOKLASSE (gemäß Anhang VIII (EU) 2017/745)**

Class <i>Klasse</i>	I	Conformity Assessment Procedure <i>Konformitätsbewertungsverfahren</i>
Rule <i>Regel</i>	1	Art. 52, Para. 7 Art. 52, Para. 7

**A complete listing of applied standards is available upon request.
 Eine vollständige Liste der angewandten Normen ist auf Anfrage verfügbar.**





EU-Declaration of Conformity

EU-Konformitätserklärung

The Manufacturer declares that the above-mentioned products meet the provision of the following EU legislation.
Der Hersteller erklärt, dass die oben genannten Produkte den Bestimmungen folgender EU-Gesetzgebung entsprechen.

(EU) 2017/745 MDR

This declaration is valid until / *Diese Erklärung ist gültig bis zum:* 17.12.2025

Tuttlingen, 05.07.2021

p.p. Karim Djamshidi-Gilani
Executive Director / Global Regulatory Affairs

This declaration instantly loses all validity in consequence of any product change not authorized by KARL SE & Co. KG in written form, in case of product change affects the conformity to the General Safety and Performance Requirements, so that a new placing on the market must be assumed.

Diese Erklärung verliert sofort ihre Gültigkeit in Folge jeder nicht durch KARL STORZ SE & Co. KG schriftlich autorisierten Änderung am Produkt, bei der die Konformität mit den Grundlegenden Sicherheits- und Leistungsanforderungen beeinflusst wird, so dass von einem neuen Inverkehrbringen auszugehen ist.

SAP ID: 300000420274

Version: BB



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KARL STORZ — ENDOSKOPE

EU-Declaration of Conformity

EU-Konformitätserklärung

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Diese Europäische Konformitätserklärung wird in alleiniger Verantwortung des Herstellers ausgestellt.

**MANUFACTURER
 HERSTELLER**

Name of Company <i>Firmen Name</i>	Address <i>Adresse</i>	SRN <i>SRN</i>
KARL STORZ SE & Co. KG	Dr.-Karl-Storz-Str. 34 78532 Tuttlingen Germany	DE-MF-000005723

**PRODUCT IDENTIFICATION
 PRODUKTIDENTIFIZIERUNG**

Device Description <i>Produkt Bezeichnung</i>	Basic UDI-DI <i>Basis UDI-DI</i>
Sealing cap, metal, plastic	4048551000087TJ

**Intended use
 Zweckbestimmung**

Sealing caps are used for closing the proximal openings of rigid bronchoscopes, tracheoscopes, and esophagoscopes. Sealing caps are non-invasive and are designed for transient use in surgically invasive procedures or invasive procedures through a body orifice.

**REF Number(s), Short text
 REF Nummer(n), Kurztext**

10338P FLUVOG Adaptor, movable, 10315P FLUVOG Adaptor, adjustable, 10314P FLUVOG Adaptor, movable

**RISK CLASS (according Annex VIII (EU) 2017/745)
 RISIKOKLASSE (gemäß Anhang VIII (EU) 2017/745)**

Class <i>Klasse</i>	Conformity Assessment Procedure <i>Konformitätsbewertungsverfahren</i>
I	
Rule <i>Regel</i>	Conformity Assessment Procedure <i>Konformitätsbewertungsverfahren</i>
1	Art. 52, Para. 7 Art. 52, Para. 7

**A complete listing of applied standards is available upon request.
 Eine vollständige Liste der angewandten Normen ist auf Anfrage verfügbar.**





EU-Declaration of Conformity

EU-Konformitätserklärung

The Manufacturer declares that the above-mentioned products meet the provision of the following EU legislation.
Der Hersteller erklärt, dass die oben genannten Produkte den Bestimmungen folgender EU-Gesetzgebung entsprechen.

(EU) 2017/745 MDR

This declaration is valid until / *Diese Erklärung ist gültig bis zum:* 17.12.2025.

Tuttlingen, 05.07.2021

p.p. Karin Djamshidi-Gilani
Executive Director / Global Regulatory Affairs

This declaration instantly loses all validity in consequence of any product change not authorized by KARL SE & Co. KG in written form, in case of product change affects the conformity to the General Safety and Performance Requirements, so that a new placing on the market must be assumed.

Diese Erklärung verliert sofort ihre Gültigkeit in Folge jeder nicht durch KARL STORZ SE & Co. KG schriftlich autorisierten Änderung am Produkt, bei der die Konformität mit den Grundlegenden Sicherheits- und Leistungsanforderungen beeinflusst wird, so dass von einem neuen Inverkehrbringen auszugehen ist.

SAP ID: 300000416160

Version: BB



STORZ

KARL STORZ — ENDOSKOPE

EU-Declaration of Conformity

EU-Konformitätserklärung

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.
Diese Europäische Konformitätserklärung wird in alleiniger Verantwortung des Herstellers ausgestellt.

**MANUFACTURER
 HERSTELLER**

Name of Company <i>Firmen Name</i>	Address <i>Adresse</i>	SRN <i>SRN</i>
KARL STORZ SE & Co. KG	Dr.-Karl-Storz-Str. 34 78532 Tuttlingen Germany	DE-MF-000005723

**PRODUCT IDENTIFICATION
 PRODUKTIDENTIFIZIERUNG**

Device Description <i>Produkt Bezeichnung</i>	Basic UDI-DI <i>Basis UDI-DI</i>
Telescope, compact cystoscope	4048551000525TM

**Intended use
 Zweckbestimmung**

The telescope is used for endoscopic imaging and, if necessary, for creating a working or irrigation channel during endourological diagnosis and treatment. Compact cystoscopes are used for endoscopic imaging of the urethra and bladder for the purposes of diagnosis and treatment. The integrated working channel allows for the use of flexible or semirigid auxiliary instruments such as forceps, stone baskets, etc., coagulation electrodes and laser fibers for lithotripsy or for the ablation of benign/malignant tissue. Telescopes/compact cystoscopes are designed for transient use in invasive interventions through a body orifice.

**REF Number(s), Short text
 REF Nummer(n), Kurztext**

27301AA HOPKINS Telescope 0°, 1.9 mm, 27033AA Miniature Telescope 0°, 1.2 mm, 20 cm, 27017AA HOPKINS Telescope 0°, 1.9/2.1 mm, 27017BA HOPKINS Telescope 30°, 1.9/2.1mm, 18cm, 27018CA HOPKINS Telescope 70°, 2.7mm, 18cm, 27018BA HOPKINS Telescope 30°, 2.7 mm, 18 cm, 27018AA HOPKINS Telescope 0°, 2.7mm, 27301BA HOPKINS Telescope 30°, 1.9mm



STORZ

KARL STORZ — ENDOSKOPE

EU-Declaration of Conformity

EU-Konformitätserklärung

RISK CLASS (according Annex VIII (EU) 2017/745)
RISIKOKLASSE (gemäß Anhang VIII (EU) 2017/745)

Class Klasse	1	Conformity Assessment Procedure Konformitätsbewertungsverfahren
Rule Regel	5	Art. 52, Para. 7 Art. 52, Para. 7

A complete listing of applied standards is available upon request.
Eine vollständige Liste der angewandten Normen ist auf Anfrage verfügbar.

The Manufacturer declares that the above-mentioned products meet the provision of the following EU legislation.
Der Hersteller erklärt, dass die oben genannten Produkte den Bestimmungen folgender EU-Gesetzgebung entsprechen.

(EU) 2017/745 MDR

This declaration is valid until / *Diese Erklärung ist gültig bis zum:* 17.12.2025.

Tuttlingen, 06.07.2021


p.p. Karim Djanshid-Gilani
Executive Director / Global Regulatory Affairs

This declaration instantly loses all validity in consequence of any product change not authorized by KARL SE & Co. KG in written form, in case of product change affects the conformity to the General Safety and Performance Requirements, so that a new placing on the market must be assumed.

Diese Erklärung verliert sofort ihre Gültigkeit in Folge jeder nicht durch KARL STORZ SE & Co. KG schriftlich autorisierten Änderung am Produkt, bei der die Konformität mit den Grundlegenden Sicherheits- und Leistungsanforderungen beeinflusst wird, so dass von einem neuen Inverkehrbringen auszugehen ist.

SAP ID: 300000420313
Version: BB