



# Certificate

No. Q5 084462 0038 Rev. 06

**Holder of Certificate: KARL STORZ SE & Co. KG**

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

**Certification Mark:**



**Scope of Certificate: Design and development, production, sales 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)
- Imaging Systems (Camera Heads, CCUs, Monitors, Exoscopes)
- Implants (Nonactive implants for ENT (sterile), Nonactive 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)
- Insufflators, Tubing Sets (sterile/non-sterile)
- Laser (Laser Devices, Foot Switches for Laser, Laser Fibers (sterile/non-sterile))
- Lithotriptors (Lithotripsy Devices, Foot Switches for Lithotripsy Devices, Lithotripsy Probes (sterile/non-sterile))
- Morcellator Systems and Accessories for Endoscopic Therapy

# Certificate

No. Q5 084462 0038 Rev. 06

## Scope of Certificate:

- 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
- Sheaths, Trocars (sterile/non sterile)
- 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
- 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)
- Insufflators/Tubing Sets
- Laser (Laser Devices, Foot Switches for Laser, Laser Fibers)
- Lithotriptors (Lithotripsy Devices, Foot Switches for 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

# Certificate

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## Scope of Certificate:

- Pumps (Pumps, Foot Switches for Pumps, Tubing Sets)
- Retaining Systems
- Sheaths, Trocars
- Videoendoscopes (Rigid Videoscopes with and without channel, Flexible Videoscopes with and without channel)

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:Q5 084462 0038 Rev. 06](http://www.tuvsud.com/ps-cert?q=cert:Q5 084462 0038 Rev. 06)

Report No.: 713206531

Valid from: 2022-06-02

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Date, 2022-06-02



Christoph Dicks

Head of Certification/Notified Body

# Certificate

**No. Q5 084462 0038 Rev. 06**

<b>Applied Standard(s):</b>	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) DIN EN ISO 13485:2016
<b>Facility(ies):</b>	<b>Storz Endoskop Produktions GmbH</b> <b>Schneckenackerstr. 1, 8200 Schaffhausen, SWITZERLAND</b>  See Scope of Certificate  <b>KARL STORZ SE &amp; Co. KG</b> <b>Dr.-Karl-Storz-Straße 11, 78532 Tuttlingen, GERMANY</b>  See Scope of Certificate  <b>KARL STORZ SE &amp; Co. KG</b> <b>Elsa-Brandström-Weg 21, 78532 Tuttlingen, GERMANY</b>  See Scope of Certificate  <b>KARL STORZ SE &amp; Co. KG</b> <b>take-off Gewerbepark 44-47, 78579 Neuhausen ob Eck,</b> <b>GERMANY</b>  See Scope of Certificate  <b>KARL STORZ SE &amp; Co. KG</b> <b>Kaiserstraße 10, 78532 Tuttlingen, GERMANY</b>  See Scope of Certificate  <b>KARL STORZ SE &amp; Co. KG</b> <b>Dr.-Karl-Storz-Straße 34, 78532 Tuttlingen, GERMANY</b>  See Scope of Certificate  <b>KARL STORZ SE &amp; Co. KG</b> <b>take-off Gewerbepark 83, 78579 Neuhausen ob Eck,</b> <b>GERMANY</b>  See Scope of Certificate  <b>KARL STORZ SE &amp; Co. KG</b> <b>Friedrich-List-Straße 6, 76297 Stutensee, GERMANY</b>  See Scope of Certificate  <b>KARL STORZ SE &amp; Co. KG</b> <b>Scharnhorststraße 3, 10115 Berlin, GERMANY</b>  See Scope of Certificate



Product Service

# Certificate

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Facility(ies):

**KARL STORZ Video Endoscopy Estonia OÜ**  
**Pärnu maantee 556b, Laagri, 76401 Harju maakond, ESTONIA**

See Scope of Certificate

**KARL STORZ SE & Co. KG**  
**Unter Buchsteig 8, 78532 Tuttlingen-Möhringen, GERMANY**

See Scope of Certificate

# Certificate

**No. Q5 084462 0038 Rev. 06**

## Facilities:

**KARL STORZ SE & Co. KG**  
**Elsa-Brandström-Weg 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 (sterile/non-sterile)))
- Catheters (sterile/non-sterile)
- Cannulas (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 Working Elements)
- Sheaths, Trocars (sterile/non-sterile)

**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 (Lithotripsy Devices, Foot Switches for Lithotripsy Devices, Lithotripsy Probes (sterile/-non-sterile))
- Illumination Systems (Light Sources, Light Cables, Light Carrier, Head Lamps, Battery Light Sources)
- Retaining Systems

### Servicing regarding maintenance of reusable active medical devices

- Data Storage, Data Management and Routing Systems, Active controlling systems
- Lithotriptors (Lithotripsy Devices, Foot Switches for Lithotripsy Devices, Lithotripsy Probes (non-sterile))
- Illumination Systems (Light Sources, Light Cables, Light Carrier, Head Lamps, Battery Light Sources)
- Laser (Laser Devices, Foot Switches for Laser Devices)

# Certificate

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**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

## Sales and 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 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)
- 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 (Nonactive implants for ENT (sterile), Nonactive bone implants for arthroscopic procedures (sterile), Bioabsorbable implants for arthroscopic procedures (sterile), Surgical suture material for arthroscopic procedures (sterile))

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



# Certificate

**No. Q5 084462 0038 Rev. 06**

**Storz Endoskop Produktions GmbH  
Schneckenackerstrasse 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 for Lithotripsy Devices, Lithotripsy Probes (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)
- 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 for Pumps, Tubing Sets (non-sterile))
- Insufflators, Tubing Sets (non-sterile)

## Servicing regarding maintenance of reusable active and non-active medical devices

- Optics (Rigid Endoscopes with and without channel)
- Imaging Systems (Camera Heads, CCUs, Monitors, Exoscopes)
- Pumps (Pumps, Foot Switches for Pumps)
- Insufflators

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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 (Nonactive implants for ENT (sterile), Nonactive 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)
- Lithotriptors (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)
- 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)

# Certificate

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

**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

# Certificate

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**KARL STORZ SE & Co. KG**  
take-off Gewerbepark 44-47  
78579 Neuhausen ob Eck  
Germany

Production (including final Cleaning, final Packaging) of active and non-active medical devices

- Instruments (Instruments with movable jaws/Instruments without movable jaws (sterile/non-sterile)), Working Elements Inserts, (Suction/Irrigation Instruments (sterile/non-sterile))
- Catheters (sterile/non-sterile)
- Cannulas (sterile/non-sterile)
- 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 (sterile/non-sterile)

**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

# Certificate

No. Q5 084462 0038 Rev. 06

**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)

**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
- Lithotriptors (Lithotripsy Devices, Foot Switches for Lithotripsy Devices, Lithotripsy Probes (sterile/non-sterile))
- Illumination Systems (Light Sources, Light Cables, Light Carrier, Head Lamps, Battery Light Sources)

# Certificate

**No. Q5 084462 0038 Rev. 06**

**KARL STORZ SE & Co. KG**  
**Dr.-Karl-Storz-Straße 11**  
**78532 Tuttlingen**  
**Germany**

Design and development, 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 (sterile/non-sterile)))
- Catheters (sterile/non-sterile)
- Cannulas (sterile/non-sterile)
- Sheaths and Trocars (sterile/non-sterile)
- Implants (Nonactive implants for ENT (sterile), Nonactive 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 Devices, Foot Switches for Lithotripsy Devices, Lithotripsy Probes (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)
- Hygiene/Cleaning (Sterilization Trays/Perforated Baskets)
- Imaging Systems (Exoscopes)