



# Certificate

No. Q5 084462 0038 Rev. 01

**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, distribution, sales, installation and servicing of active medical devices (non sterile, sterile), non-active medical devices (non sterile, sterile), implants (non sterile, sterile)**

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). See also notes overleaf.

**Report No.:** 713142937

**Valid from:** 2019-06-01

**Valid until:** 2022-05-31

**Date,** 2019-05-29

Stefan Preiß  
Head of Certification/Notified Body

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<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>	KARL STORZ Beteiligungs GmbH Mittelstrasse 8, 78532 Tuttlingen, GERMANY  Storz Endoskop Produktions GmbH Schneckenackerstr. 1, 8200 Schaffhausen, SWITZERLAND  KARL STORZ SE & Co. KG Dr.-Karl-Storz-Straße 11, 78532 Tuttlingen, GERMANY  KARL STORZ SE & Co. KG Carl-von-Linde-Straße 15, 85748 Garching, GERMANY  KARL STORZ SE & Co. KG Elsa-Brandström-Weg 21, 78532 Tuttlingen, GERMANY  KARL STORZ SE & Co. KG take-off Gewerbepark 44-47, 78579 Neuhausen ob Eck, GERMANY  KARL STORZ SE & Co. KG Kaiserstraße 10, 78532 Tuttlingen, GERMANY  KARL STORZ SE & Co. KG Dr.-Karl-Storz-Straße 34, 78532 Tuttlingen, GERMANY  KARL STORZ SE & Co. KG take-off Gewerbepark 83, 78579 Neuhausen ob Eck, GERMANY  KARL STORZ SE & Co. KG Friedrich-List-Straße 6, 76297 Stutensee, GERMANY  KARL STORZ SE & Co. KG Scharnhorststraße 3, 10115 Berlin, GERMANY  KARL STORZ Video Endoscopy Estonia OÜ Pärnu maantee 556b, Laagri, 76401 Harju maakond, ESTONIA

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## Facilities:

**KARL STORZ Beteiligungs GmbH**  
Mittelstrasse 8  
78532 Tuttlingen  
Germany

Management

**KARL STORZ SE & Co. KG**  
Elsa-Brandström-Weg 21  
78532 Tuttlingen  
Germany

Production of non-active medical devices

Products in scope:

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

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

Design and development, production and servicing of active medical devices,  
non-active medical devices and implants and sterile medical devices

Products in scope:

- Instruments (Instruments with movable jaws, Instruments without movable jaws, Working Elements/Working Inserts, Suction/Irrigation Instruments, Catheters, Cannulas)
- Sheaths and Trocars
- Implants (Nonactive implants for ENT (S), Nonactive bone implants for arthroscopic procedures (S), Bioabsorbable implants for arthroscopic procedures (S), Surgical suture material for arthroscopic procedures (S))
- HOPKINS Optics (HOPKINS Telescopes with channel, HOPKINS Telescopes without channel)
- Fiberscopes and semiflexible endoscopes (Fiberscopes with channel, Fiberscopes without channel, Semiflexible endoscopes with channel, Semiflexible endoscopes without channel)
- Videoendoscopes (Rigid Videoscopes with channel, Rigid Videoscopes without channel, Flexible Videoscopes with channel, Flexible Videoscopes without channel)
- Retaining Systems
- Equipment Carts
- Lithotriptors (Lithotripsy Devices, Foot Switches Lithotripsy Devices, Lithotripsy Probes)
- 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)
- Hygiene/Cleaning (Sterilization Trays/Perforated Baskets)

**KARL STORZ SE & Co. KG**  
Kaiserstraße 10  
78532 Tuttlingen  
Germany

Design and development, production of active medical devices, non-active medical devices,  
servicing of active medical devices (non sterile)

Products in scope:

- OR1 (Data Storage, Data Management and Routing Systems, Active controlling systems)
- Lithotriptors (Lithotripsy Devices, Foot Switches Lithotripsy Devices, Lithotripsy Probes)
- Illumination Systems (Light Sources, Light Cables, Light Carrier, Head Lamps, Battery Light Sources)

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

Design and development, distribution, sales, installation and servicing of active medical devices (non sterile, sterile), non-active medical devices (non sterile, sterile), implants (non sterile, sterile)

**Products in scope:**

- Implants (Nonactive implants for ENT (S), Nonactive bone implants for arthroscopic procedures (S), Bioabsorbable implants for arthroscopic procedures (S), Surgical suture material for arthroscopic procedures (S))
- HOPKINS Optics (HOPKINS Telescopes with channel, HOPKINS Telescopes without channel)
- Fiberscopes and semiflexible endoscopes (Fiberscopes with channel, Fiberscopes without channel, Semiflexible endoscopes with channel, Semiflexible endoscopes without channel)
- Videoendoscopes (Rigid Videoscopes with channel, Rigid Videoscopes without channel, Flexible Videoscopes with channel, Flexible Videoscopes without channel)
- Retaining Systems
- Equipment Carts
- Imaging Systems (Camera Heads, CCUs, Monitors)
- Lithotriptors (Lithotripsy Devices, Foot Switches Lithotripsy Devices, Lithotripsy Probes)
- Pumps (Pumps, Foot Switches 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 Switch Laser, Laser Fibers)
- Motors (Motor Control Unit, Handpieces/Motors, Foot Switches Motor Control Unit, Shaver/Drills)
- Morcellator Systems and Accessories for Endoscopic Therapy
- OR1 (Data Storage, Data Management and Routing Systems, Active controlling systems)
- 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)
- Hygiene/Cleaning (Sterilization Trays/Perforated Baskets)

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**Storz Endoskop Produktions GmbH**  
Schneckenackerstrasse 1  
8200 Schaffhausen  
Switzerland

Design and development, production, installation and servicing of active medical devices,  
non-active medical devices

Products in scope:

- HOPKINS Optics (HOPKINS Telescopes with channel, HOPKINS Telescopes without channel)
- Fiberscopes and semiflexible endoscopes (Fiberscopes with channel, Fiberscopes without channel, Semiflexible endoscopes with channel, Semiflexible endoscopes without channel)
- Videoendoscopes (Rigid Videoscopes with channel, Rigid Videoscopes without channel, Flexible Videoscopes with channel, Flexible Videoscopes without channel)
- Retaining Systems
- Equipment Carts
- Imaging Systems (Camera Heads, CCUs, Monitors)
- Lithotriptors (Lithotripsy Devices, Foot Switches Lithotripsy Devices, Lithotripsy Probes)
- Pumps (Pumps, Foot Switches 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)
- Motors (Motor Control Unit, Handpieces/Motors, Foot Switches 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)
- Insufflators/Tubing Sets
- Instruments (Instruments with movable jaws, Instruments without movable jaws, Working Elements/Working Inserts, Suction/Irrigation Instruments, Catheters, Cannulas)
- Navigation (Navigation Units, EM Navigation)

**KARL STORZ SE & Co. KG**  
Carl-von-Linde-Straße 15  
85748 Garching  
Germany

Service and Repair of Flexible Endoscopes for Diagnosis and Therapy (non sterile)

Products in scope:

- Videoendoscopes (Flexible Videoscopes with channel, Flexible Videoscopes without channel)

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**No. Q5 084462 0038 Rev. 01**

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

Distribution and servicing of active medical devices (non sterile, sterile),  
 non-active medical devices (non sterile, sterile), implants (non sterile, sterile)

Products in scope:

- Implants (Nonactive implants for ENT (S), Nonactive bone implants for arthroscopic procedures (S), Bioabsorbable implants for arthroscopic procedures (S), Surgical suture material for arthroscopic procedures (S))
- HOPKINS Optics (HOPKINS Telescopes with channel, HOPKINS Telescopes without channel)
- Fiberscopes and semiflexible endoscopes (Fiberscopes with channel, Fiberscopes without channel, Semiflexible endoscopes with channel, Semiflexible endoscopes without channel)
- Videoscopes (Rigid Videoscopes with channel, Rigid Videoscopes without channel, Flexible Videoscopes with channel, Flexible Videoscopes without channel)
- Retaining Systems
- Equipment Carts
- Imaging Systems (Camera Heads, CCUs, Monitors)
- Lithotriptors (Lithotripsy Devices, Foot Switches Lithotripsy Devices, Lithotripsy Probes)
- Pumps (Pumps, Foot Switches 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 Switch Laser, Laser Fibers)
- Motors (Motor Control Unit, Handpieces/Motors, Foot Switches Motor Control Unit, Shaver/Drills)
- Morcellator Systems and Accessories for Endoscopic Therapy
- OR1 (Data Storage, Data Management and Routing Systems, Active controlling systems)
- 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)
- Hygiene/Cleaning (Sterilization Trays/Perforated Baskets)

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

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

Products in scope:

- Instruments (Instruments with movable jaws, Instruments without movable jaws, Working Elements/Working Inserts, Suction/Irrigation Instruments, Catheters, Cannulas)
- HOPKINS Optics (HOPKINS Telescopes with channel, HOPKINS Telescopes without channel)

**KARL STORZ SE & Co. KG**  
Scharnhorststraße 3  
10115 Berlin  
Germany

Design and Development of robotic systems for surgical assistance and of software for clinical workflows, documentation, data management, interoperability and communication

Products in scope:

- Retaining Systems
- OR1 (Data Storage, Data Management and Routing Systems, Active controlling systems)



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**KARL STORZ SE & Co. KG**  
Friedrich-List-Straße 6  
76297 Stutensee  
Germany

Production, installation and servicing of Medical Device Communication Systems

Products in scope:

- OR1 (Data Storage, Data Management and Routing Systems, Active controlling systems)

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

Design and development, production and servicing of active and non-active medical devices and components (non sterile)

Products in scope:

- Videoendoscopes (Rigid Videoscopes with channel, Rigid Videoscopes without channel, Flexible Videoscopes with channel, Flexible Videoscopes without channel)