



Certificate

No. Q5 084462 0038 Rev. 04

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/Catheters/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

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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. 04

Report No.: 713196404

Valid from: 2020-09-23

Valid until: 2022-05-31

Date, 2020-09-30



Christoph Dicks
Head of Certification/Notified Body

Certificate

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Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

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

Central functions related to the quality management system

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

Production of 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 (sterile/non-sterile)))

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/Catheters/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

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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 Cables, HF Generators, HF Foot Switches, HF Working Elements)
- Hygiene/Cleaning (Sterilization Trays/Perforated Baskets)
- Imaging Systems (Exoscopes)

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

- Instruments (Instruments with movable jaws/Instruments without movable jaws, 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, Flexible Videoscopes with and without channel)
- Retaining Systems
- Equipment Carts
- Lithotriptors (Lithotripsy Devices, Foot Switches for 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)
- Imaging Systems (Exoscopes)

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

Design and development, 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)

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)
- 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 of active medical devices

- Data Storage, Data Management and Routing Systems, Active controlling systems, components of software

Sales, 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/Catheters/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)

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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 (sterile/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, Tubing Sets)

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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 (steril/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/Catheters/Cannulas (sterile/non-sterile)))
- Sheaths, Trocars (sterile/non-sterile)
- Navigation (Navigation Units, EM Navigation)
- Hygiene/Cleaning (Sterilization Trays/Perforated Baskets)

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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)
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- 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)

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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/Working Inserts, (Suction/Irrigation Instruments/Catheters/Cannulas (sterile/non-sterile)))
- Optics (Rigid Endoscopes with and without channel)
- Imaging Systems (Exoscopes)

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

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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

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

Design and development and production of active and non-active medical devices

- Videoendoscopes (Rigid Videoscopes with and without channel, Flexible Videoscopes with and without channel)
- Components of Videoendoscopes

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

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

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

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

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