



Certificate

No. Q5 084462 0038 Rev. 10

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

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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
- 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

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Scope of Certificate: 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
- 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)

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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, Certification, Validation and Verification Regulations 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. 10](http://www.tuvsud.com/ps-cert?q=cert:Q5_084462_0038_Rev.10)

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Valid from: 2024-04-08

Valid until: 2025-05-31

Date, 2024-04-08



Christoph Dicks

Head of Certification/Notified Body

Certificate

No. Q5 084462 0038 Rev. 10

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **Storz Endoskop Produktions GmbH**
Schneckenackerstr. 1, 8200 Schaffhausen, SWITZERLAND

See Scope of Certificate

KARL STORZ SE & Co. KG
Dr.-Karl-Storz-Straße 11, 78532 Tuttlingen, GERMANY

See Scope of Certificate

KARL STORZ SE & Co. KG
Elsa-Brandström-Weg 11 & 21, 78532 Tuttlingen, GERMANY

See Scope of Certificate

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

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KARL STORZ SE & Co. KG
Kaiserstraße 10, 78532 Tuttlingen, GERMANY

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

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

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KARL STORZ SE & Co. KG
Friedrich-List-Straße 6, 76297 Stutensee, GERMANY

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KARL STORZ SE & Co. KG

Scharnhorststraße 3, 10115 Berlin, GERMANY

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KARL STORZ Video Endoscopy Estonia OÜ

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

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KARL STORZ SE & Co. KG

Unter Buchsteig 8, 78532 Tuttlingen-Möhringen, GERMANY

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Storz Endoskop Produktions GmbH

Ernst-Müller Strasse 8, 8200 Schaffhausen, SWITZERLAND

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Facilities:

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 Pumps, Tubing Sets (sterile/non-sterile))
- 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)
- 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
Dr.-Karl-Storz-Straße 11
78532 Tuttlingen
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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 (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 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 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)

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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)
- Illumination Systems (Light Cables, Light Carrier, Head Lamps, Components for Illumination Systems)

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
- 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)

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)

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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)

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 Lithotripsy Devices)
- Illumination Systems (Light Sources)
- Retaining Systems
- HF Systems (HF Foot Switches)
- Motors (Foot Switches Motor Control Unit)
- Laser (Foot Switches 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 Laser)

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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 Lithotripsy Devices, Lithotripsy Probes (sterile/non-sterile))
- Pumps (Pumps, Foot Switches 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 Laser, Laser Fibers (sterile/non-sterile))
- Motors (Motor Control Unit, Handpieces/Motors, Foot Switches 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 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
- 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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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 Lithotripsy Devices, Lithotripsy Probes (sterile/non-sterile))
- Pumps (Pumps, Foot Switches 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 Laser, Laser Fibers (sterile/non-sterile))
- Motors (Motor Control Unit, Handpieces/Motors, Foot Switches 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)

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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 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
- 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)

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

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- 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)

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

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 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 (steril/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)
- Illumination Systems (Light Sources, Light Cables, Light Carrier, Head Lamps, Battery Light Sources)
- Imaging Systems (CCUs)

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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 for 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)