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D-ZM-11321-01-00

TÜV SÜD
Product Service

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:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

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

Digitally signed by Cucerenco Olesea
Date: 2019.10.22 15:58:35 EEST
Reason: MoldSign Signature
Location: Moldova

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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

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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Product Service

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No. Q5 084462 0038 Rev. 01

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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No. Q5 084462 0038 Rev. 01

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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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)
- 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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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)

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