



America

# CERTIFICATE

No. QS6 084462 0044 Rev. 02

**Certificate Holder:**

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

**Certification Mark:**



**Scope of Certificate:**

**See Page 2 - 3 for Overall Scope Statement.**

**Standard(s):**

**ISO 13485:2016**

**Regulatory Authority(ies):**

**Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website [www.tuvsud.com/ps-cert](http://www.tuvsud.com/ps-cert)

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**DUNS No:**

**31-573-1430**

**Effective Date:**

**2020-09-09**

**Expiry Date:**

**2022-05-09**

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## Regulatory Requirements: Audit/Certification Criteria

### Australia

Therapeutic Goods (Medical Devices) Regulations 2002  
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

### Brazil

- RDC ANVISA n. 16/2013  
- RDC ANVISA n. 23/2012  
- RDC ANVISA n. 67/2009

### Canada

- Medical Device Regulations – Part 1- SOR 98/282

### Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68  
- PMD Act

### United States

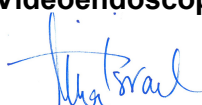
- 21 CFR Part 803  
- 21 CFR Part 806  
- 21 CFR Part 807 – Subparts A to D  
- 21 CFR Part 820  
- 21 CFR Part 821

## Overall Scope Statement:

**Design, Development, Production, Servicing, Installation and Distribution Products in Scope:**  
**Implants (Non-Active Implants for ENT (S), Non-Active 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**

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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 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), Sheath, Trocars, Navigation (Navigation Units, EM Navigation), Hygiene / Cleaning (Sterilization Trays / Perforated Baskets)

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**Facility(ies):**

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

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

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

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

KARL STORZ Beteiligungs GmbH  
Mittelstrasse 8, 78532 Tuttlingen, GERMANY

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

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

Storz Endoskop Produktions GmbH  
Schneckenackerstr. 1, 8200 Schaffhausen, SWITZERLAND

KARL STORZ SE & Co. KG  
Scharnhorststraße 3, 10115 Berlin, GERMANY

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

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

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## Facility Scopes:

### 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): Implants (Non-Active Implants for ENT (S), Non-Active 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 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), Sheath, Trocars, Navigation (Navigation Units, EM Navigation), Hygiene / Cleaning (Sterilization Trays / Perforated Baskets)  
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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: Instruments (Instruments with Movable Jaws, Instruments without Movable Jaws, Working Elements/Working Inserts, Suction / Irrigation Instruments, Catheters, Cannulas), Sheath, Trocars, Implants (Non-Active Implants for ENT (S), Non-Active 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)

DUNS No: 31-359-0362

**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, Working Elements / Working Inserts, Suction / Irrigation Instruments, Catheters, Cannulas)

DUNS No: 31-359-0360

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## 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): 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)  
 DUNS No: 31-359-0363

## KARL STORZ Beteteiligungs GmbH

Mittelstrasse 8, 78532 Tuttlingen, GERMANY

Management  
 DUNS No: 31-765-2469

## KARL STORZ SE & Co. KG

take-off Gewerbepark 83, 78579 Neuhausen ob Eck, GERMANY

Logistics Center; Distribution and Servicing of Active Medical Devices (Non-Sterile, Sterile), Non-Active Medical Devices (Non-Sterile, Sterile), Implants (Non-Sterile, Sterile): Implants (Non-Active Implants for ENT (S), Non-Active 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,

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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 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), Sheath, Trocars, Navigation (Navigation Units, EM Navigation), Hygiene / Cleaning (Sterilization Trays / Perforated Baskets)  
 DUNS No: 31-316-6330

## KARL STORZ SE & Co. KG

take-off Gewerbepark 44-47, 78579 Neuhausen ob Eck, GERMANY

Production of Components for Non-Active Medical Devices (Non-Sterile); Cleaning and Packing of Final Products: 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)  
 DUNS No: 31-359-0367

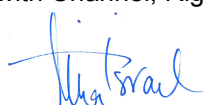
## Storz Endoskop Produktions GmbH

Schneckenackerstr. 1, 8200 Schaffhausen, SWITZERLAND

Design and Development, Production, Installation and Servicing of Active Medical Devices, Non-Active Medical Devices: 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

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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 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)  
DUNS No: 48-108-1156

**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: Retaining Systems, OR1 (Data Storage, Data Management and Routing Systems, Active Controlling Systems)  
DUNS No: 31-977-1325

**KARL STORZ SE & Co. KG**

Friedrich-List-Straße 6, 76297 Stutensee, GERMANY

Production, Installation and Servicing of Medical Device Communication Systems: OR1 (Data Storage, Data Management and Routing Systems, Active Controlling Systems)  
DUNS No: 31-359-0368

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**KARL STORZ Video Endoscopy Estonia OÜ**

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

Design and Development, Production and Servicing of  
Active and Non-Active Medical Devices and Components  
(Non-Sterile): Videoendoscopes (Rigid Videoscopes with  
Channel, Rigid Videoscopes without Channel, Flexible  
Videoscopes with Channel, Flexible Videoscopes without Channel)  
DUNS No: 64-728-9441

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