



CERTIFICATE

No. QS6 084462 0044 Rev. 03

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

REPs Facility ID:

F001257

Effective Date:

2022-05-19

Expiry Date:

2025-05-09

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Medical and Health Services



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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 and Development, Production 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 (Non-Active Implants for ENT (Sterile), Non-Active 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

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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), Insufflators, Tubing Sets (Sterile / Non-Sterile), Laser (Laser Devices, Foot Switch for Laser, Laser Fibers (Sterile / Non-Sterile), 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, 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, Sheaths, Trocars, Insufflators, Tubing Sets, Laser (Laser Devices, Foot Switch for Laser, Laser Fibers), 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, Videoendoscopes (Rigid Videoscopes with and without Channel, Flexible Videoscopes with and without Channel)

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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 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 SE & Co. KG
Unter Buchsteig 8, 78532 Tuttlingen-Möhringen, 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 of Active Medical Devices: Data Storage, Data Management and Routing Systems, Active Controlling Systems, Components of Software; 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), Lithotripsy (Lithotripsy Devices, Foot Switches 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 Switch 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 (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 (Non-Active Implants for ENT (Sterile), Non-Active Bone Implants for Arthroscopic Procedures (Sterile), Bioabsorbable Implants for Arthroscopic Procedures (Sterile), Surgical Suture Material for Arthroscopic Procedures (Sterile); 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), Lithotripsy (Lithotripsy Devices, Foot Switches

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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))
REPs Facility ID: F001257

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 (Sterile / Non-Sterile)), Catheters (Sterile / Non-Sterile), Cannulas (Sterile / Non-Sterile), Sheaths and Trocars (Sterile / Non-Sterile), Implants (Non-Active Implants for ENT (Sterile), Non-Active 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 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), Hygiene / Cleaning (Sterilization Trays / Perforated Baskets), Imaging Systems (Exoscopes)
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KARL STORZ SE & Co. KG

Elsa-Brandström-Weg 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 (Sterile / Non-Sterile)), Catheters (Sterile / Non-Sterile), Cannulas (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), Sheaths, Trocars (Sterile / Non-Sterile) REPs Facility ID: F001257

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 (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), Retaining Systems; 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 (Non-Sterile)), Illumination Systems (Light Sources, Light Cables, Light Carrier, Head Lamps, Battery Light Sources), Laser (Laser Devices, Foot Switches for Laser Devices) REPs Facility ID: F001257

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 (Non-Active Implants for ENT (Sterile), Non-Active 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

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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 (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; 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), 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,

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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 Inserts, (Suction / Irrigation Instruments (Sterile / Non-Sterile)), Catheters (Sterile / Non-Sterile), Cannulas (Sterile / Non-Sterile), 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 (Sterile / Non-Sterile)
REPs Facility ID: F001257

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 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

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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 (Non-Sterile)), Insufflators, Tubing Sets (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), Insufflators
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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
REPs Facility ID: F002171

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
REPs Facility ID: F002170

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, Lithotripsy Probes (Sterile / Non-Sterile)), Illumination Systems (Light Sources, Light Cables, Light Carrier, Head Lamps, Battery Light Sources)
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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 (Sterile / 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)
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