



America

CERTIFICATE

No. QS6 18 06 84462 020

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

Certification Mark:



Scope of Certificate: See page 2 for Overall Scope.

Standard(s): ISO 13485:2016

Regulatory Authority: 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

<http://www.tuv-sud-america.com/us-en/resource-center/customer-support/certificate-finder>

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

DUNS No: 31-459-0364

Effective Date: 2018-06-29

Expiry Date: 2019-05-23

Manuel Bradaric
 MHS Certification Manager



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No. QS6 18 06 84462 020

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

Overall Scope:

Design and Development, Manufacturing, Distribution, Installation and Service of Medical and Surgical Instruments for Open Procedures, Medical and Surgical Instruments for Endoscopic Procedures (Diagnosis and Therapy), Active Surgery Instruments, Titanium Implants for ENT, Laparoscopic and Arthroscopic Procedures, Bioabsorbable Implants for Arthroscopic Procedures, Implantable Clamps for Ligation of Tubings and Vessels, Rigid, Semi-Rigid and Flexible Endoscopes for Diagnosis and Therapy, Holding Systems and Mobile Carts, Data Management Software, Camera Systems and Accessories for Endoscopic Diagnosis and Therapy, Lithotripters and Accessories for Endoscopic Therapy, High Frequency Surgical Devices and Accessories for Endoscopic Therapy, Motor Systems and Accessories for Endoscopic Therapy, Morcellator Systems and Accessories for Endoscopic Therapy, Operating Room Control Systems and Related Software, Light Sources and Accessories for Endoscopic Therapy, Insufflators and Accessories for Endoscopic Therapy, Suction and Irrigation Systems and Accessories for Endoscopic Therapy, Navigation Systems and Accessories for Endoscopic Therapy, Monitors and Accessories for Endoscopic Purposes, Sterilization Trays and Accessories for Cleaning Purposes

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

Design, Development, Distribution and Service of Medical and Surgical Instruments for Open Procedures; Medical and Surgical Instruments for Endoscopic Procedures (Diagnosis and Therapy); Active Surgery Instruments; Titanium Implants for ENT, Laparoscopic and Arthroscopic Procedures; Bioabsorbable Implants for Arthroscopic Procedures, Implantable Clamps for Ligation of Tubings and Vessels; Rigid, Semi-rigid and Flexible Endoscopes for Diagnosis and Therapy; Holding Systems and Mobile Carts; Data Management Software; Camera Systems and Accessories for Endoscopic Diagnosis and Therapy; Lithotripters and Accessories for Endoscopic Therapy; High Frequency Surgical Devices and Accessories for Endoscopic Therapy; Motor Systems and Accessories for Endoscopic Therapy; Morcellator Systems and Accessories for Endoscopic Therapy; Operating Room Control Systems and Related Software; Light Sources and Accessories for Endoscopic Therapy; Insufflators and Endoscopic Therapy; Navigation Systems and Accessories for Endoscopic Therapy; Monitors and Accessories for Endoscopic Purposes; Sterilization Trays and Accessories for Cleaning Purposes

KARL STORZ Beteiligungs GmbH
Mittelstrasse 8
78532 Tuttlingen
GERMANY

Management

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

Distribution and Service of Medical and Surgical Instruments for Open Procedures;
 Medical and Surgical Instruments for Endoscopic Procedures (Diagnosis and Therapy);
 Active Surgery Instruments; Titanium Implants for ENT, Laparoscopic and Arthroscopic
 Procedures; Bioabsorbable Implants for Arthroscopic Procedures; Implantable Clamps
 for Ligation of Tubings and Vessels; Rigid, Semi-rigid and Flexible Endoscopes for Diagnosis
 and Therapy; Holding Systems and Mobile Carts; Data Management Software; Camera Systems
 and Accessories for Endoscopic Diagnosis and Therapy; Lithotripters and Accessories for
 Endoscopic Therapy; High Frequency Surgical Devices and Accessories for Endoscopic Therapy;
 Motor Systems and Accessories for Endoscopic Therapy; Morcellator Systems and Accessories
 for Endoscopic Therapy; Operating Room Control Systems and Related Software; Light Sources
 and Accessories for Endoscopic Therapy; Insufflators and Endoscopic Therapy; Navigation
 Systems and Accessories for Endoscopic Therapy; Monitors and Accessories for Endoscopic
 Purposes; Sterilization Trays and Accessories for Cleaning Purposes

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

Manufacturing and Service of Medical and Surgical Instruments for Endoscopic Procedures
 (Diagnosis and Therapy); Medical and Surgical Instruments for Open Procedures; Medical
 and Surgical Instruments for Endoscopic Procedures (Diagnosis and Therapy)

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

Design, Development, Manufacturing and Service of Medical and Surgical Instruments for Endoscopic Procedures (Diagnosis and Therapy); Medical and Surgical Instruments for Open Procedures; Medical and Surgical Instruments for Endoscopic Procedures (Diagnosis and Therapy); Active Surgery Instruments; Titanium Implants for ENT, Laparoscopic and Arthroscopic Procedures; Bioabsorbable Implants for Arthroscopic Procedures; Implantable Clamps for Ligation of Tubings and Vessels; Rigid, Semi-rigid and Flexible Endoscopes for Diagnosis and Therapy; Holding Systems and Mobile Carts; Lithotripters and Accessories for Endoscopic Therapy; High Frequency Surgical Devices and Accessories for Endoscopic Therapy; Sterilization Trays and Accessories for Cleaning Purposes

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

Design, Development, Manufacturing and Service of Light Sources and Accessories for Endoscopic Diagnosis and Therapy; Endoscopic Video Unit and Accessories for Endoscopic Diagnosis and Therapy; Data Management Systems; Operating Room Control Systems; Lithotripters and Accessories for Endoscopic Therapy

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

Manufacturing and Service of Flexible Endoscopes for Diagnosis and Therapy

Effective Date: **2018-06-29**
 Expiry Date: **2019-05-23**

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

Manufacturing of Components for Medical and Surgical Instruments for Endoscopic Procedures; Medical and Surgical Instruments for Open Surgical Procedures; Rigid Endoscopes for Diagnosis and Therapy; Packaging of: Medical and Surgical Instruments for Endoscopic Procedures; Medical and Surgical Instruments for Open Surgical Procedures

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

Project Planning, Production, Installation and Servicing of Medical Device Communication Systems; the OR1 Products are Designed to Allow Transfer Selection of Audio/Video Signals, Medical Images, Interface Signals and Control Signals from Various Commercially Available Instruments and Medical Devices that are Commonly used in a Medical Procedure Laboratory or Operating Room; the Products Allow Selection of these Signals from a Central Point

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

Design and Development of Software for Robotic Systems for Surgical Assistance and Software for Clinical Workflows, Documentation, Data Management, Interoperability and Communication

Effective Date: 2018-06-29
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No. QS6 18 06 84462 020

Storz Endoskop Produktions GmbH
Schneckenackerstrasse 1
8200 Schaffhausen
SWITZERLAND

Design, Development, Manufacturing, Distribution, Installation and Service of Medical and Surgical Instruments for Open Procedures; Medical and Surgical Instruments for Endoscopic Procedures (Diagnosis and Therapy); Active Surgery Instruments; Titanium Implants for ENT, Laparoscopic and Arthroscopic Procedures; Bioabsorbable Implants for Arthroscopic Procedures; Implantable Clamps for Ligation of Tubings and Vessels; Rigid, Semi-rigid and Flexible Endoscopes for Diagnosis and Therapy; Holding Systems and Mobile Carts; Data Management Software; Camera Systems and Accessories for Endoscopic Diagnosis and Therapy; Lithotripters and Accessories for Endoscopic Therapy; High Frequency Surgical Devices and Accessories for Endoscopic Therapy; Motor Systems and Accessories for Endoscopic Therapy; Morcellator Systems and Accessories for Endoscopic Therapy; Operating Room Control Systems and Related Software; Light Sources and Accessories for Endoscopic Therapy; Insufflators and Accessories for Endoscopic Therapy; Suction and Irrigation Systems and Accessories for Endoscopic Therapy; Navigation Systems and Accessories for Endoscopic Therapy; Monitors and Accessories for Endoscopic Purposes

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

Design, Development, Production and Servicing of Flexible Endoscopes for Diagnosis and Therapy; Flexible and Rigid Video Endoscopes for Diagnosis and Therapy

Effective Date: 2018-06-29
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Audit/Certification Criteria

Australia

- Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1
- Schedule 3, Part 4

Brazil

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

Canada

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

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820
- 21 CFR Part 821

Japan

- MHLW Ministerial Ordinance No.169, 2004

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