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Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 18 04 84462 012

Manufacturer:

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

Facility(ies):

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

Product Category(ies):

- **medical and surgical instruments**
- **active surgical instruments**
- **implantable clamps for ligation of tubings and vessels**
- **bone implants (non active)**
- **rigid and flexible endoscopes for diagnostics and therapy**
- **active medical devices and surgical auxiliary devices**
- **cameras, devices and auxiliary devices for imaging procedure with non ionizing radiation**

[for a detailled list of product groups class II a and higher we refer to the KARL STORZ internal document C2.3.1 (in the current updated version)]

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713129927

Valid from: 2018-07-17
Valid until: 2023-07-16

Date, 2018-07-03

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

SOCIETATEA COMERCIALA S.R.L. "DENOLGA MEDICAL" IDNO 1005600059558 REPUBLICA MOLDOVA

Digitally signed by Cucerenco Olesea
Date: 2019.03.18 10:35:29 EET
Reason: MoldSign Signature
Location: Moldova

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A1 / 07.17

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America

CERTIFICATE

No. QS5 16 06 11325 423

Certificate Holder: Karl Storz GmbH & Co. KG
Mittelstrasse 8
78532 Tuttlingen
GERMANY

Certification Mark:

Scope of Certificate: See page 2 for overall scope statement

Standard(s): ISO 9001:2008

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.: M2631

Effective Date: 2016-06-14
Expiry Date: 2019-05-23

Gary Minks
Vice President, Regulatory Affairs

TÜV SÜD America Inc.
10 Centennial Drive
Peabody, MA 01960
USA

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SOCIETATEA COMERCIALA S.R.L. "DENOLA MEDICAL" IDNO 1005600059558 REPUBLICA MOLDOVA

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America

CERTIFICATE

No. QS5 16 06 11325 423

Karl Storz GmbH & Co. KG
Mittelstrasse 8
78532 Tuttlingen
GERMANY

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

Karl Storz GmbH & Co. KG
Take off Gerwerbepark 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, 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:	**2016-06-14**
Expiry Date:	**2019-05-23**

Gary Minks
Vice President, Regulatory Affairs

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SOCIETATEA COMERCIALA S.R.L. "DENTAL MEDICA" IDNO 1005600059458 REPUBLICA MOLDOVA
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TÜV SÜD America

CERTIFICATE

No. QS5 16 06 11325 423

Karl Storz GmbH & Co. KG
Elsa Brandström Weg 21
78532 Tuttlingen
GERMANY

Manufacturing 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)

Karl Storz GmbH & Co. KG
Dr. Karl-Storz-Straße 11
78532 Tuttlingen
GERMANY

Design and Development, Manufacturing 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 GmbH & Co. KG
Kaiserstraße 10
78532 Tuttlingen
GERMANY

Design and Development, Manufacturing 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

Effective Date:	**2016-06-14**
Expiry Date:	**2019-05-23**

Gary Minks
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CERTIFICATE

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Karl Storz GmbH & Co. KG
Carl-von-Linde-Straße 15
85748 Garching
GERMANY

Manufacturing and Service of Flexible Endoscopes for Diagnosis and Therapy

Karl Storz GmbH & Co. KG
Take off Gerwerbepark 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

Effective Date:	2016-06-14
Expiry Date:	2019-05-23

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SOCIETATEA COMERCIALĂ "DENOL MEDICAL" S.R.L.
IDNO 1005600059558 REPUBLICA MOLDOVA

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TÜV SÜD America

CERTIFICATE

No. QS5 16 06 11325 423

Karl Storz GmbH & Co. KG
Friedrich List Straße 6
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Project Planning, Production, Installation and Servicing of Medical Device Communication Systems

Karl Storz - Endoskope Berlin GmbH
Scharnhorststraße 3
10115 Berlin

Design and Development of Software for Robotic Systems

Storz Endoskop Produktions GmbH
Schneckenackerstrasse 1
8200 Schaffhausen/Schweiz
SWITZERLAND

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

Storz Endoskop Produktions GmbH
Ernst-Müller Strasse 8
8200 Schaffhausen/Schweiz
SWITZERLAND

Design and Development, Manufacturing and Service of Rigid, Semi-Rigid and Flexible Endoscopes for Diagnosis and Therapy, Data Management Software, Operating Room Control Systems and Related Software

Effective Date:	2016-06-14
Expiry Date:	2019-05-23

Gary Minks
Vice President, Regulatory Affairs

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SOCIETATEA COMERCIALA S.R.L. "DENOLGA MEDICAL" IDNO 1005600059556 REPUBLICA MOLDOVA
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America

CERTIFICATE

No. QS6 16 05 11325 424

Certificate Holder: Karl Storz GmbH & Co. KG
Mittelstrasse 8
78532 Tuttlingen
GERMANY

Certification Mark:

Scope of Certificate: See page 2 for overall scope statement

Standard(s): ISO 13485:2003

Regulatory Authority: TGA, ANVISA, Health Canada, 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 Authorized Auditing Organization.

DUNS No:	31-573-1430
Effective Date:	2016-05-24
Expiry Date:	2019-05-23

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Gary Minks
Vice President, Regulatory Affairs

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No. QS6 16 05 11325 424

Audit/Certification Criteria

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

Brazil
- Federal Law n. 6360/76
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009
- RDC ANVISA n. 56/2001

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

Japan
- MHLW Ministerial Ordinance No.169, 2004

Effective Date: 2016-05-24
Expiry Date: 2019-05-23

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