



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
BS-MDR-099



Product Service

## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class IIa and Class IIb Devices)

**No. G10 084462 0072 Rev. 05**

### Manufacturer:

**KARL STORZ SE & Co. KG**

Dr.-Karl-Storz-Straße 34  
78532 Tuttlingen  
GERMANY

SRN Manufacturer - DE-MF-000005723

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.

For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G10 084462 0072 Rev. 05](http://www.tuvsud.com/ps-cert?q=cert:G10 084462 0072 Rev. 05)

**Report No.:** 713280463

**Preceding Certificate No.:** G10 084462 0072 Rev. 04

**Valid from:** 2025-04-10

**Valid until:** 2025-12-17

**Date of Initial Issuance:** 2020-12-18

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2025-04-10



## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class IIa and Class IIb Devices)

**No. G10 084462 0072 Rev. 05**

<b>Classification:</b>	Class IIa
<b>Device Group:</b>	A018099 - NEEDLES - OTHER ACCESSORIES
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	A060102 - SURGICAL DRAINAGE CONNECTION MEDICAL TUBES
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	A060399 - FLUID COLLECTION BAGS AND SYSTEMS - OTHER
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	K010101 - TROCAR, SINGLE-USE
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	K010201 - MINIMALLY INVASIVE SURGERY SURGICAL INSTRUMENTS, SINGLE-USE
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	K030203 - ARTHROSCOPY BLADES, SINGLE-USE
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	K030299 - ARTHROSCOPY SURGICAL INSTRUMENTS, SINGLE USE - OTHER
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	L0102 - SURGICAL KNIVES, REUSABLE
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	L030101 - SUCTION AND IRRIGATION SURGICAL CANNULAS AND HANDPIECES, REUSABLE
<b>Intended Purpose:</b>	./.



## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class IIa and Class IIb Devices)

**No. G10 084462 0072 Rev. 05**

<b>Classification:</b>	Class IIa
<b>Device Group:</b>	L030199 - GENERAL SURGERY SURGICAL CANNULAS AND HANDPIECES, REUSABLE - OTHER
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	L031202 - ABDOMINAL TROCAR, REUSABLE
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	L031203 - OTOLARYNGOLOGICAL SURGERY TROCAR, REUSABLE
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	L031301 - GENERAL SURGERY BIOPSY FORCEPS, REUSABLE
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	L031401 - GENERAL SURGERY SPREADERS AND RETRACTORS, REUSABLE
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	L0399 - GENERAL SURGERY INSTRUMENTS, REUSABLE - OTHER
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	L050903 - GYNECOLOGICAL SURGERY FORCEPS, REUSABLE
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	L059099 - OBSTETRICS AND GYNECOLOGY INSTRUMENTS, REUSABLE - OTHER
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa



## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class IIa and Class IIb Devices)

**No. G10 084462 0072 Rev. 05**

<b>Device Group:</b>	L080501 - BRONCHUS CLAMPS, REUSABLE
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	L0899 - THORACIC SURGERY INSTRUMENTS, REUSABLE - OTHER
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	L0916 - ORTHOPAEDIC SURGERY BURS AND TIPS, REUSABLE
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	L1206 - LAPAROSCOPIC AND THORACOSCOPIC SURGERY SPREADERS AND RETRACTORS, REUSABLE
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	L140202 - NASAL AND PARANASAL CAVITY SURGERY PLIERS, REUSABLE
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	L140402 - TRACHEOTOMY INSTRUMENTS, REUSABLE
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	L149002 - ENT LEVERS, REUSABLE
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	L149003 - ENT RETRACTORS, REUSABLE
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	L149007 - ENT SPOONS, REUSABLE
<b>Intended Purpose:</b>	./.



## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class IIa and Class IIb Devices)

**No. G10 084462 0072 Rev. 05**

<b>Classification:</b>	Class IIa
<b>Device Group:</b>	L149099 - ENT INSTRUMENTS, REUSABLE - OTHER
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	L180102 - ENDOSCOPIC ELECTROSURGERY DISSECTORS, REUSABLE
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	Q030302 - ENT SURGERY BURS AND HANDPIECES, SINGLE-USE
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	U090101 - URINARY STONE RETRIEVAL BASKETS
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	U090199 - URINARY STONE RETRIEVAL DEVICES - OTHER
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	U090303 - UROGENITAL ENDOSCOPY BRUSHES
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	U090399 - SINGLE-USE INSTRUMENTS FOR UROGENITAL ENDOSCOPY - OTHER
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	Z120109 - ELECTROSURGICAL INSTRUMENTS
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	Z120110 - LASER SURGERY INSTRUMENTS
<b>Intended Purpose:</b>	./.



## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class IIa and Class IIb Devices)

**No. G10 084462 0072 Rev. 05**

<b>Classification:</b>	Class IIa
<b>Device Group:</b>	Z120114 - SURGICAL NAVIGATION INSTRUMENTS
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	Z120190 - VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	Z120202 - MOTORISED INSTRUMENTS FOR ENDOSCOPIC SURGERY
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	Z120203 - ENDOSCOPIC LITHOTRIPSY INSTRUMENTS
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	Z120204 - INSTRUMENTS FOR THE ACQUISITION AND MANAGEMENT OF ENDOSCOPIC AND MINIMALLY INVASIVE SURGERY IMAGES
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	Z120205 - UPPER GASTROINTESTINAL TRACT ENDOSCOPY INSTRUMENTS
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	Z120206 - LOWER GASTROINTESTINAL TRACT ENDOSCOPY INSTRUMENTS
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	Z120207 - GENITOURINARY ENDOSCOPY INSTRUMENTS
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	Z120208 - PULMONARY ENDOSCOPIC INSTRUMENTS



## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class IIa and Class IIb Devices)

**No. G10 084462 0072 Rev. 05**

**Intended Purpose:** ./.

**Classification:** Class IIa  
**Device Group:** Z120210 - ENT ENDOSCOPY INSTRUMENTS  
**Intended Purpose:** ./.

**Classification:** Class IIa  
**Device Group:** Z120211 - ORTHOPAEDIC ENDOSCOPY INSTRUMENTS  
**Intended Purpose:** ./.

**Classification:** Class IIa  
**Device Group:** Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND  
MINI-INVASIVE SURGERY  
**Intended Purpose:** ./.

**Classification:** Class IIa  
**Device Group:** Z120802 - GYNAECOLOGY AND FERTILITY TREATMENT  
INSTRUMENTS  
**Intended Purpose:** ./.

**Classification:** Class IIa  
**Device Group:** Z121305 - MOTORISED ORTHOPAEDIC SURGERY SYSTEM  
INSTRUMENTS  
**Intended Purpose:** ./.

**Classification:** Class IIa  
**Device Group:** Z121601 - EXTRACORPOREAL LITHOTRIPSY INSTRUMENTS  
**Intended Purpose:** ./.

**Classification:** Class IIa  
**Device Group:** Z121690 - VARIOUS INSTRUMENTS FOR UROLOGY  
**Intended Purpose:** ./.

**Classification:** Class IIa  
**Device Group:** Z129099 - VARIOUS INSTRUMENTS FOR FUNCTIONAL  
EXPLORATION AND THERAPEUTIC INTERVENTIONS - OTHER  
**Intended Purpose:** ./.

**Classification:** Class IIb





## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class IIa and Class IIb Devices)

**No. G10 084462 0072 Rev. 05**

<b>Device Group:</b>	Z120109 - ELECTROSURGICAL INSTRUMENTS
<b>Intended Purpose:</b>	Footswitches are intended to activate and control functions of medical devices. Footswitches do not have body contact.
<b>Classification:</b>	Class IIb
<b>Device Group:</b>	Z120109 - ELECTROSURGICAL INSTRUMENTS
<b>Intended Purpose:</b>	High-frequency generators are intended to provide electrical power for high-frequency surgical application parts. High-frequency generators do not have body contact.
<b>Classification:</b>	Class IIb
<b>Device Group:</b>	Z120109 - ELECTROSURGICAL INSTRUMENTS
<b>Intended Purpose:</b>	HF Electrodes are intended for cutting, coagulation or vaporization of tissue.
<b>Classification:</b>	Class IIb
<b>Device Group:</b>	Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY
<b>Intended Purpose:</b>	The footswitches are used to activate and control the functions of medical devices
<b>Classification:</b>	Class IIb
<b>Device Group:</b>	Z120203 - ENDOSCOPIC LITHOTRIPSY INSTRUMENTS
<b>Intended Purpose:</b>	CALCUSPLIT probes are intended to guide pneumatic pulse energy for lithotripsy to the calculus. Probes are surgically invasive and meant for short term use.
<b>Classification:</b>	Class IIb
<b>Device Group:</b>	Z120203 - ENDOSCOPIC LITHOTRIPSY INSTRUMENTS
<b>Intended Purpose:</b>	Laser units are intended to provide laser radiation for cutting, coagulation, vaporization and ablation of biological tissue, as well as for lithotripsy of stones during surgical procedures. Laser units do not have body contact.
<b>Classification:</b>	Class IIb
<b>Device Group:</b>	Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY
<b>Intended Purpose:</b>	Insufflators with heating are intended to deliver and heat CO2 for insufflation (creating and maintaining a cavity) or replacement of ambient air in laparoscopy, thoracoscopy, transanal endoscopy and endoscopic vessel harvesting. Insufflators are non-invasive and meant for short-term use.





## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class IIa and Class IIb Devices)

**No. G10 084462 0072 Rev. 05**

**Classification:** Class IIb  
**Device Group:** Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY  
**Intended Purpose:** The device is used to centrally display and enable remote control of the parameters.

**Classification:** Class IIb  
**Device Group:** Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY  
**Intended Purpose:** Insufflators with heating and smoke evacuation are intended to deliver and heat CO2 for insufflation and smoke evacuation. Insufflators with heating and smoke evacuation are non-invasive and meant for short-term use.

**Classification:** Class IIb  
**Device Group:** Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY  
**Intended Purpose:** Heated tubing sets with filter for insufflation are intended for filtration, transfer and heating of CO2 from the insufflator to the patient. Heated tubing sets with filter for insufflation are non-invasive and meant for short-term use

**Classification:** Class IIb  
**Device Group:** Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY  
**Intended Purpose:** Heated tubing sets with filter for insufflation and smoke evacuation are intended for filtration, transfer and heating of CO2 from the insufflator to the patient as well as filtration and transfer of smoke from the patient to the insufflator. Heated tubing sets with filter for insufflation and smoke evacuation are non-invasive and meant for short-term use.

**Classification:** Class IIb  
**Device Group:** Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY  
**Intended Purpose:** Heated and humidified tubing sets with filter for insufflation and smoke evacuation are intended for filtration, transfer, heating and humidification of CO2 from the insufflator to the patient as well as filtration and transfer of smoke from the patient to the insufflator. Heated and humidified tubing sets with filter for insufflation and smoke evacuation are non-invasive and meant for short-term use.

**Classification:** Class IIb  
**Device Group:** Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND



## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class IIa and Class IIb Devices)

**No. G10 084462 0072 Rev. 05**

**Intended Purpose:** MINI-INVASIVE SURGERY  
Smart Smoke Evacuation is intended to communicate the level of surgical smoke to the insufflator. Smart Smoke Evacuation does not have body contact

**Classification:** Class IIb  
**Device Group:** Z120190 - VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY

**Intended Purpose:** Suction/irrigation pumps are intended to irrigate irrigation fluid into organs, joints and on fields of intervention, as well as to suction off irrigation and body fluids, secretions, tissue and gases. Suction/irrigation pumps do not have body contact.

**Classification:** Class IIb  
**Device Group:** Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY

**Intended Purpose:** Insufflators are intended to deliver CO2 for insufflation (creating and maintaining a cavity) or replacement of ambient air in laparoscopy, thoracoscopy, ransanal endoscopy and endoscopic vessel harvesting. Insufflators are non-invasive and meant for short-term use

**The validity of this certificate depends on conditions and/or is limited to the following:** - none -

### Revision History:

Rev.	Dated	Report	Description
00	2020-12-18	713169106	-
01	2022-04-14	713224270	-
02	2022-09-22	713249165	-
03	2023-09-27	713253483 / 713274574	Supplemented: Device(s)/group of device(s) added
04	2023-11-23	713300338	Supplemented: Device(s)/group of device(s) added
05	2025-04-10	713280463	Supplemented: Device(s)/group of device(s) added



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www.zlg.de  
BS-MDR-099



Product Service

## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

**No. G11 084462 0071 Rev. 00**

### Manufacturer:

**KARL STORZ SE & Co. KG**

Dr.-Karl-Storz-Straße 34  
78532 Tuttlingen  
GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).

The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. As applicable the involvement of the notified body is limited to the aspects relating to:

- establishing, securing and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.

For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G11 084462 0071 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:G11_084462_0071_Rev_00)

**Report No.:** 713169106

**Valid from:** 2020-12-17

**Valid until:** 2025-12-16

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2020-12-17



## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

**No. G11 084462 0071 Rev. 00**

**Classification:** I  
**Device Properties:** MDS 1006 - Reusable surgical instruments  
**Device Group:** MDN 1208 - Non-active non-implantable instruments

**Classification:** I  
**Device Properties:** MDS 1005.1 - Ethylen oxyde sterilization  
MDS 1005.2 - Sterilisation by irradiation  
**Device Group:** MDN 1208 - Non-active non-implantable instruments

**Classification:** I  
**Device Properties:** MDS 1005.1 - Ethylen oxyde sterilization  
MDS 1005.2 - Sterilisation by irradiation  
**Device Group:** MDN 1202 - Non-active non-implantable devices for  
administration, channelling and removal of substances, including  
devices for dialysis

**The validity of this certificate depends on conditions and/or is limited to the following:** - none -



Product Service

# Certificate

No. Q5 084462 0038 Rev. 12

**Holder of Certificate:** **KARL STORZ SE & Co. KG**

Dr.-Karl-Storz-Straße 34  
78532 Tuttlingen  
GERMANY

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production and Distribution of**

- sterile, non-sterile and reusable non-active instruments and related accessories (e.g. surgical instruments, rigid, flexible and semiflexible endoscopes, sheaths and trocars, shaver and drills, retaining systems and equipment carts) for the area of surgical treatments and diagnostics
- sterile, non-sterile and reusable non-active devices for administration, channelling and removal of substances and related accessories (e.g. suction and irrigation instruments, cannulas and catheters, tubing sets) for the area of surgical treatments and diagnostics
- sterile, non-sterile and reusable active surgical devices and related accessories (e.g. electrosurgical generators with their applications, pumps and insufflation devices, motor systems with its applications, and devices incorporating software) for the area of electrosurgical applications, surgical treatments and diagnostics
- sterile, non-sterile and reusable active devices for imaging systems, light sources and related accessories (e.g. illumination systems, light sources, imaging systems, CCUs and rigid and flexible videoendoscopes) for the area of endoscopic and general treatments
- active devices utilising non-ionizing radiation (e.g. laser and ultrasound lithotripsy devices) for the area of surgical treatment (ENT, thoracic and general surgery, gynecology, gastroenterology and urology)
- active medical devices (e.g. footswitches, software and components) for the area of electrosurgical applications, surgical treatments and diagnostics
- non-active medical devices (e.g. sterilization trays and perforated baskets) for the area of reprocessing and storage



Product Service

# Certificate

No. Q5 084462 0038 Rev. 12

## Servicing of

- non-active instruments and related accessories (e.g. surgical instruments, rigid, flexible and semiflexible endoscopes, sheaths and trocars, shaver and drills, retaining systems and equipment carts) for the area of surgical treatments and diagnostics
- non-active devices for administration, channelling and removal of substances and related accessories (e.g. suction and irrigation instruments, cannulas and catheters, tubing sets) for the area of surgical treatments and diagnostics
- active surgical devices and related accessories (e.g. electrosurgical generators with their applications, pumps and insufflation devices, motor systems with its applications, and devices incorporating software) for the area of electrosurgical applications, surgical treatments and diagnostics
- active devices for imaging systems, light sources and related accessories (e.g. illumination systems, light sources, imaging systems, CCUs and rigid and flexible videoendoscopes) for the area of endoscopic and general treatments
- active devices utilising non-ionizing radiation (e.g. laser and ultrasound lithotripsy devices) for the area of surgical treatment (ENT, thoracic and general surgery, gynecology, gastroenterology and urology)
- active medical devices (e.g. footswitches, software and components) for the area of electrosurgical applications, surgical treatments and diagnostics
- non-active medical devices (e.g. sterilization trays and perforated baskets) for the area of reprocessing and storage

**Installation of active devices and related accessories (solutions consisting of hardware and software) in clinical environment**



Deutsche  
Akkreditierungsstelle  
D-ZM-11321-01-00



Product Service

# Certificate

No. Q5 084462 0038 Rev. 12

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). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 084462 0038 Rev. 12](http://www.tuvsud.com/ps-cert?q=cert:Q5 084462 0038 Rev. 12)

Report No.: 713352668

Valid from: 2025-06-01

Valid until: 2028-05-31

Date, 2025-05-28

Christoph Dicks  
Head of Certification/Notified Body





Product Service

# Certificate

No. Q5 084462 0038 Rev. 12

**Applied Standard(s):** ISO 13485:2016  
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)  
Medical devices - Quality management systems -  
Requirements for regulatory purposes

**Facility(ies):** **KARL STORZ SE & Co. KG**  
Dr.-Karl-Storz-Straße 34, 78532 Tuttlingen, GERMANY

Design and Development, Marketing, Sales and Servicing  
regarding customer support of medical devices (see overall scope)

Installation of active devices and related accessories

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

Design and Development of medical devices (see overall scope)

Production of sterile, non-sterile and reusable non-active  
instruments and related accessories; sterile, non-sterile and  
reusable non-active devices for administration, channelling and  
removal of substances and related accessories; sterile, non-sterile  
and reusable active surgical devices and related accessories;  
reusable active devices for imaging systems, light sources and  
related accessories and other active medical devices

**KARL STORZ SE & Co. KG**  
Elsa-Brandström-Weg 11 & 21, 78532 Tuttlingen, GERMANY

Production of sterile, non-sterile and reusable non-active  
instruments and related accessories; reusable non-active devices  
for administration, channelling and removal of substances and  
related accessories; reusable active surgical devices and related  
accessories and other active medical devices

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

Production of reusable non-active instruments and related  
accessories; reusable active surgical devices and related  
accessories; active devices for imaging systems, light sources and  
related accessories and other active medical devices

**KARL STORZ SE & Co. KG**  
Unter Buchsteig 8, 78532 Tuttlingen-Möhringen, GERMANY

Design and Development of non-active instruments and related  
accessories; active surgical devices and related accessories;  
active devices for imaging systems, light sources and related  
accessories and other active medical devices



Product Service

# Certificate

No. Q5 084462 0038 Rev. 12

## KARL STORZ SE & Co. KG

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

Central functions related to quality management system

Distribution of medical devices (see overall scope)

Maintenance service of medical devices (see overall scope)

Final cleaning and non-sterile final packaging of medical devices (see overall scope)

Metal and Plastic processing of components for active and non-active instruments and medical devices

## KARL STORZ SE & Co. KG

Scharnhorststraße 3, 10115 Berlin, GERMANY

Design and Development of active medical devices incorporating software

## KARL STORZ Video Endoscopy Estonia OÜ

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

Design and Development of sterile, non-sterile and reusable active devices for imaging systems, light sources and related accessories

Production of sterile, non-sterile and reusable non-active instruments and related accessories; non-active devices for administration, channelling and removal of substances and related accessories and reusable active devices for imaging systems, light sources and related accessories

Maintenance service of active devices for imaging systems, light sources and related accessories

## Storz Endoskop Produktions GmbH

Schneckenackerstr. 1, 8200 Schaffhausen, SWITZERLAND

Design and Development of reusable non-active instruments and related accessories; sterile, non-sterile and reusable non-active devices for administration, channelling and removal of substances and related accessories; sterile, non-sterile and reusable active surgical devices and related accessories; reusable active devices for imaging systems, light sources and related accessories and other active medical devices



Product Service

# Certificate

No. Q5 084462 0038 Rev. 12

## Facility(ies):

Production of reusable non-active instruments and related accessories; reusable non-active devices for administration, channelling and removal of substances and related accessories; active surgical devices and related accessories; active devices for imaging systems, light sources and related accessories and other active medical devices

### **Storz Endoskop Produktions GmbH**

Ernst-Müller-Strasse 8, 8200 Schaffhausen, SWITZERLAND

Servicing of active medical devices (see overall scope)

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