



## 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. 04**

**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 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:G10 084462 0072 Rev. 04](http://www.tuvsud.com/ps-cert?q=cert:G10_084462_0072_Rev.04)

**Report No.:** 713300338  
**Preceding Certificate No.:** G10 084462 0072 Rev. 03  
**Valid from:** 2023-11-23  
**Valid until:** 2025-12-17  
**Date of Initial Issuance:** 2020-12-18

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2023-11-23



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<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>	./.



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<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



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<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>	./.



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



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<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



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<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	Z120210 - ENT ENDOSCOPY INSTRUMENTS
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	Z120211 - ORTHOPAEDIC ENDOSCOPY INSTRUMENTS
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	Z120802 - GYNAECOLOGY AND FERTILITY TREATMENT INSTRUMENTS
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	Z121305 - MOTORISED ORTHOPAEDIC SURGERY SYSTEM INSTRUMENTS
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	Z121601 - EXTRACORPOREAL LITHOTRIPSY INSTRUMENTS
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	Z121690 - VARIOUS INSTRUMENTS FOR UROLOGY
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	Z129099 - VARIOUS INSTRUMENTS FOR FUNCTIONAL EXPLORATION AND THERAPEUTIC INTERVENTIONS - OTHER
<b>Intended Purpose:</b>	./.
<b>Classification:</b>	Class IIb



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**No. G10 084462 0072 Rev. 04**

<b>Device Group:</b>	L180602 - ENDOSCOPIC ELECTROSURGERY ELECTRODES, REUSABLE
<b>Intended Purpose:</b>	HF-Electrodes are intended for cutting, coagulation or vaporization of tissue. HF-Electrodes are surgically invasive and meant for short term use.
<b>Classification:</b>	Class IIb
<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>	Z120190 - VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY
<b>Intended Purpose:</b>	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.
<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.





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<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, Othoracoscopy, transanal endoscopy and endoscopic vessel harvesting. Insufflators are non-invasive and meant for short-term use.
<b>Classification:</b>	Class IIb
<b>Device Group:</b>	Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY
<b>Intended Purpose:</b>	The device is used to centrally display and enable remote control of the parameters.
<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 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.
<b>Classification:</b>	Class IIb
<b>Device Group:</b>	Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY
<b>Intended Purpose:</b>	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
<b>Classification:</b>	Class IIb
<b>Device Group:</b>	Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY
<b>Intended Purpose:</b>	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.
<b>Classification:</b>	Class IIb
<b>Device Group:</b>	Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND



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**Intended Purpose:** MINI-INVASIVE SURGERY  
 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 MINI-INVASIVE SURGERY

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

**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