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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. 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

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

Digitally signed by Gherman Irina
Date: 2024.10.29 15:50:47 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-11-23

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No. G10 084462 0072 Rev. 04

Classification:	Class IIa
Device Group:	A018099 - NEEDLES - OTHER ACCESSORIES
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	A060102 - SURGICAL DRAINAGE CONNECTION MEDICAL TUBES
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	A060399 - FLUID COLLECTION BAGS AND SYSTEMS - OTHER
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	K010101 - TROCAR, SINGLE-USE
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	K010201 - MINIMALLY INVASIVE SURGERY SURGICAL INSTRUMENTS, SINGLE-USE
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	K030203 - ARTHROSCOPY BLADES, SINGLE-USE
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	K030299 - ARTHROSCOPY SURGICAL INSTRUMENTS, SINGLE USE - OTHER
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	L0102 - SURGICAL KNIVES, REUSABLE
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	L030101 - SUCTION AND IRRIGATION SURGICAL CANNULAS AND HANDPIECES, REUSABLE
Intended Purpose:	./.

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Classification:	Class IIa
Device Group:	L030199 - GENERAL SURGERY SURGICAL CANNULAS AND HANDPIECES, REUSABLE - OTHER
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	L031202 - ABDOMINAL TROCAR, REUSABLE
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	L031203 - OTOLARYNGOLOGICAL SURGERY TROCAR, REUSABLE
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	L031301 - GENERAL SURGERY BIOPSY FORCEPS, REUSABLE
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	L031401 - GENERAL SURGERY SPREADERS AND RETRACTORS, REUSABLE
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	L0399 - GENERAL SURGERY INSTRUMENTS, REUSABLE - OTHER
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	L050903 - GYNECOLOGICAL SURGERY FORCEPS, REUSABLE
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	L059099 - OBSTETRICS AND GYNECOLOGY INSTRUMENTS, REUSABLE - OTHER
Intended Purpose:	./.

Classification:	Class IIa

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No. G10 084462 0072 Rev. 04

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

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Classification:	Class IIa
Device Group:	L149099 - ENT INSTRUMENTS, REUSABLE - OTHER
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	L180102 - ENDOSCOPIC ELECTROSURGERY DISSECTORS, REUSABLE
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	Q030302 - ENT SURGERY BURS AND HANDPIECES, SINGLE-USE
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	U090101 - URINARY STONE RETRIEVAL BASKETS
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	U090199 - URINARY STONE RETRIEVAL DEVICES - OTHER
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	U090303 - UROGENITAL ENDOSCOPY BRUSHES
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	U090399 - SINGLE-USE INSTRUMENTS FOR UROGENITAL ENDOSCOPY - OTHER
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	Z120109 - ELECTROSURGICAL INSTRUMENTS
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	Z120110 - LASER SURGERY INSTRUMENTS
Intended Purpose:	./.

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Classification:	Class IIa
Device Group:	Z120114 - SURGICAL NAVIGATION INSTRUMENTS
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	Z120190 - VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	Z120202 - MOTORISED INSTRUMENTS FOR ENDOSCOPIC SURGERY
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	Z120203 - ENDOSCOPIC LITHOTRIPSY INSTRUMENTS
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	Z120204 - INSTRUMENTS FOR THE ACQUISITION AND MANAGEMENT OF ENDOSCOPIC AND MINIMALLY INVASIVE SURGERY IMAGES
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	Z120205 - UPPER GASTROINTESTINAL TRACT ENDOSCOPY INSTRUMENTS
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	Z120206 - LOWER GASTROINTESTINAL TRACT ENDOSCOPY INSTRUMENTS
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	Z120207 - GENITOURINARY ENDOSCOPY INSTRUMENTS
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	Z120208 - PULMONARY ENDOSCOPIC INSTRUMENTS

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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

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Device Group:	L180602 - ENDOSCOPIC ELECTROSURGERY ELECTRODES, REUSABLE
Intended Purpose:	HF-Electrodes are intended for cutting, coagulation or vaporization of tissue. HF-Electrodes are surgically invasive and meant for short term use.
Classification:	Class IIb
Device Group:	Z120109 - ELECTROSURGICAL INSTRUMENTS
Intended Purpose:	Footswitches are intended to activate and control functions of medical devices. Footswitches do not have body contact.
Classification:	Class IIb
Device Group:	Z120109 - ELECTROSURGICAL INSTRUMENTS
Intended Purpose:	High-frequency generators are intended to provide electrical power for high-frequency surgical application parts. High-frequency generators do 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 weil 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:	The footswitches are used to activate and control the functions of medical devices
Classification:	Class IIb
Device Group:	Z120203 - ENDOSCOPIC LITHOTRIPSY INSTRUMENTS
Intended Purpose:	CALCUSPLIT probes are intended to guide pneumatic pulse energy for lithotripsy to the calculus. Probes are surgically invasive and meant tor short term use.
Classification:	Class IIb
Device Group:	Z120203 - ENDOSCOPIC LITHOTRIPSY INSTRUMENTS
Intended Purpose:	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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Classification:	Class IIb
Device Group:	Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY
Intended Purpose:	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.

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

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	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 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

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