



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 020808 0039 Rev. 00

Manufacturer: **MEDICON eG**
Gänsäcker 15
78532 Tuttlingen
GERMANY

SRN Manufacturer: DE-MF-000005812

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_020808_0039_Rev._00

Report No.: 713195773

Valid from: 2022-11-09

Valid until: 2027-11-08

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-11-09



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No. G11 020808 0039 Rev. 00

Classification: I
Device Group: L010413 - MICROSURGERY SCISSORS, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L031399 - GENERAL SURGERY FORCEPS, REUSABLE - OTHER
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L0315 - GENERAL SURGERY DISSECTORS, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L031306 - HEMOSTATIC FORCEPS, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L031401 - GENERAL SURGERY SPREADERS AND RETRACTORS, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L031402 - GENERAL SURGERY SPATULAS, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L070802 - VASCULAR DILATORS, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L070801 - VASCULAR SURGERY FORCEPS, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L149099 - ENT INSTRUMENTS, REUSABLE - OTHER
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I



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Device Group: L010405 - OPHTHALMOLOGY SCISSORS, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L010499 - SURGICAL SCISSORS, REUSABLE - OTHER
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L010403 - SURGICAL DISSECTION SCISSORS, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L010404 - CARDIOVASCULAR SURGERY SCISSORS, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L031308 - SURGICAL AND ANATOMICAL TWEEZERS, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L031304 - GRASPING FORCEPS, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L1003 - MICROSURGERY FORCEPS, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L070804 - VENOUS STRIPPERS, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L0205 - NEEDLE HOLDERS, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L010412 - ORTHOPAEDIC SURGERY SCISSORS, REUSABLE



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Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L091399 - ORTHOPAEDIC SURGERY FORCEPS, REUSABLE - OTHER
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L091201 - ORTHOPAEDIC SURGERY RASPS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L091302 - BONE RONGEURS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L091303 - BONE REDUCTION FORCEPS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L090401 - ORTHOPAEDIC SURGERY OSTEOTOMES, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L080501 - BRONCHUS CLAMPS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L010103 - HANDLES FOR SCALPELS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L149005 - ENT PROBES, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L031299 - SURGICAL TROCAR, REUSABLE - OTHER
Device Properties:	MDS 1006 - Reusable surgical instruments



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Classification:	I
Device Group:	L031309 - SUTURE NEEDLE PASSERS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L031307 - TOWEL AND TUBE CLAMPS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L140499 - TRACHEA SURGERY INSTRUMENTS, REUSABLE - OTHER
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L040901 - ABDOMINAL SPREADERS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0399 - GENERAL SURGERY INSTRUMENTS, REUSABLE - OTHER
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0902 - ORTHOPAEDIC SURGERY LEVERS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0199 - SHARP INSTRUMENTS, REUSABLE - OTHER
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0999 - ORTHOPAEDIC AND TRAUMATOLOGICAL SURGERY INSTRUMENTS, REUSABLE - OTHER
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L040802 - GASTROINTESTINAL SYSTEM SPECIAL FORCEPS, REUSABLE



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Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L050803 - OBSTETRIC SURGERY FORCEPS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L040999 - ABDOMINAL SURGERY DILATORS AND SPREADERS, REUSABLE - OTHER
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L041002 - DIGESTIVE SYSTEM SURGICAL PROBES, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L041001 - LIVER AND BILIARY ROUTES SURGICAL PROBES, MULTIPURPOSE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L060603 - EXTERNAL MALE GENITALS FORCEPS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0699 - UROLOGY INSTRUMENTS, REUSABLE - OTHER
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L050802 - AMNIOTOMES, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L050804 - OBSTETRICS HOOKS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0499 - ABDOMINAL SURGERY INSTRUMENTS, REUSABLE -



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Device Properties:	OTHER MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L140599 - EAR SURGERY INSTRUMENTS, REUSABLE - OTHER
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0102 - SURGICAL KNIVES, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L149001 - ENT CURETTES, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0914 - SCOLLAPERIOSTIUM AND PERIOSTEOTOMES, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L091099 - OSTEOSYNTHESIS INSTRUMENTS, REUSABLE - OTHER
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0915 - SPREADERS AND RETRACTORS FOR ORTHOPAEDIC SURGERY, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0916 - ORTHOPAEDIC SURGERY BURS AND TIPS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L1299 - LAPAROSCOPIC AND THORACOSCOPIC INSTRUMENTS, REUSABLE - OTHER
Device Properties:	MDS 1006 - Reusable surgical instruments



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Classification:	I
Device Group:	L090901 - BONE CUTTERS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L070899 - VASCULAR SURGERY INSTRUMENTS, REUSABLE - OTHER
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L059099 - OBSTETRICS AND GYNECOLOGY INSTRUMENTS, REUSABLE - OTHER
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L031310 - DISSECTION FORCEPS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L010406 - OTOLARYNGOLOGICAL (ENT) SURGERY SCISSORS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L010411 - OBSTETRIC-GYNECOLOGICAL SURGERY SCISSORS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L091202 - ORTHOPAEDIC SURGERY FILES, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0901 - ORTHOPAEDIC SURGERY SPOONS AND CURETTES, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L090403 - ORTHOPAEDIC SURGERY GOUGES, REUSABLE



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Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L091304 - SEQUESTRIAL PLIERS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L091306 - CARTILAGE FORCEPS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L159001 - DENTAL AND PERIODONTAL CURETTES, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L040801 - LIVER AND BILIARY TRACT SPECIAL FORCEPS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L060601 - NON-ENDOSCOPIC KIDNEY FORCEPS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L060405 - ENDOSCOPIC UROLOGY SCALPELS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L060699 - NON-ENDOSCOPIC UROLOGY FORCEPS, REUSABLE - OTHER
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L050903 - GYNECOLOGICAL SURGERY FORCEPS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I



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Device Group:	L031301 - GENERAL SURGERY BIOPSY FORCEPS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L050901 - UTERINE CURETTES, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L060502 - NON-ENDOSCOPIC UROLOGY SPREADERS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L050801 - OBSTETRICS FORCEPS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L090999 - ORTHOPAEDIC SURGERY CUTTING INSTRUMENTS, REUSABLE - OTHER
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L010701 - MANUAL SURGICAL SAWS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L091102 - ORTHOPAEDIC PROSTHESES REAMERS AND BURS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L140101 - RHINOPHARYNGAL SURGERY INSTRUMENTS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L149002 - ENT LEVERS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments



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Classification:	I
Device Group:	L140602 - ENT CHISELS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L149006 - ENT PERFORATORS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L140202 - NASAL AND PARANASAL CAVITY SURGERY PLIERS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0103 - DERMOTOMES AND BLADES, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L140299 - NASAL AND PARANASAL CAVITY SURGERY INSTRUMENTS, REUSABLE - OTHER
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L140102 - OROPHARYNX SURGERY INSTRUMENTS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L091305 - FORCEPS FOR TENDONS AND LIGAMENTS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L010408 - GASTROENTEROLOGY SCISSORS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L140399 - LARYNX SURGERY INSTRUMENTS, REUSABLE - OTHER
Device Properties:	MDS 1006 - Reusable surgical instruments



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



Product Service

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No. G11 020808 0039 Rev. 00

Classification: I
Device Group: L140501 - MIDDLE EAR SURGERY INSTRUMENTS, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments

The validity of this certificate depends on conditions and/or is limited to the following: ./.