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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 I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G11 049044 0017 Rev. 01

Manufacturer:

HEBUmedical GmbH
Badstraße 8
78532 Tuttlingen
GERMANY

SRN Manufacturer - DE-MF-000009286

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 049044 0017 Rev. 01

Report No.: 713179356

Preceding Certificate No.: G11 049044 0017 Rev. 00

Valid from: 2023-05-03
Valid until: 2026-03-16

Date of Initial Issuance: 2021-03-17

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-05-03

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Classification: Class I

Device Group:
A019099 - NEEDLES FOR OTHER PROCEDURES - OTHER
A020299 - REUSABLE SYRINGES - OTHER
G020401 - HAEMORRHOID LIGATURE SETS
G030301 - POLYPECTOMY SNARES
H030102 - SINGULAR CLIPS FOR OPEN SURGERY
L010101 - MONOBLOCK SURGICAL SCALPELS, REUSABLE
L010103 - HANDLES FOR SCALPELS, REUSABLE
L0102 - SURGICAL KNIVES, REUSABLE
L0103 - DERMOTOMES AND BLADES, REUSABLE
L010402 - SURGICAL SUTURES SCISSORS, REUSABLE
L010403 - SURGICAL DISSECTION SCISSORS, REUSABLE
L010405 - OPHTHALMOLOGY SCISSORS, REUSABLE
L010406 - OTOLARYNGOLOGICAL (ENT) SURGERY SCISSORS, REUSABLE
L010408 - GASTROENTEROLOGY SCISSORS, REUSABLE
L010409 - THORACIC SURGERY SCISSORS, REUSABLE
L010411 - OBSTETRIC-GYNECOLOGICAL SURGERY SCISSORS, REUSABLE
L010412 - ORTHOPAEDIC SURGERY SCISSORS, REUSABLE
L010413 - MICROSURGERY SCISSORS, REUSABLE
L010499 - SURGICAL SCISSORS, REUSABLE - OTHER
L0107 - SURGICAL SAWS AND BLADES, REUSABLE
L0202 - SUTURE NEEDLES, REUSABLE
L030199 - GENERAL SURGERY SURGICAL CANNULAS AND HANDPIECES, REUSABLE - OTHER
L031199 - PROBES AND MIRRORS, REUSABLE - OTHER
L0312 - SURGICAL TROCAR, REUSABLE
L031301 - GENERAL SURGERY BIOPSY FORCEPS, REUSABLE
L031302 - MEDICATION FORCEPS, REUSABLE
L031303 - SWAB FORCEPS, REUSABLE
L031304 - GRASPING FORCEPS, REUSABLE
L031309 - SUTURE NEEDLE PASSERS, REUSABLE
L031310 - DISSECTION FORCEPS, REUSABLE
L031399 - GENERAL SURGERY FORCEPS, REUSABLE - OTHER
L031401 - GENERAL SURGERY SPREADERS AND RETRACTORS, REUSABLE
L031402 - GENERAL SURGERY SPATULAS, REUSABLE
L0315 - GENERAL SURGERY DISSECTORS, REUSABLE
L040801 - LIVER AND BILIARY TRACT SPECIAL FORCEPS, REUSABLE
L040802 - GASTROINTESTINAL SYSTEM SPECIAL FORCEPS, REUSABLE
L040902 - RECTAL AND ANAL SPREADERS, REUSABLE
L041002 - DIGESTIVE SYSTEM SURGICAL PROBES, REUSABLE
L050901 - UTERINE CURETTES, REUSABLE
L050903 - GYNECOLOGICAL SURGERY FORCEPS, REUSABLE
L060502 - NON-ENDOSCOPIC UROLOGY SPREADERS,

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REUSABLE
L060601 - NON-ENDOSCOPIC KIDNEY FORCEPS, REUSABLE
L060603 - EXTERNAL MALE GENITALS FORCEPS, REUSABLE
L070801 - VASCULAR SURGERY FORCEPS, REUSABLE
L080501 - BRONCHUS CLAMPS, REUSABLE
L080502 - PULMONARY CLAMPS, REUSABLE
L0901 - ORTHOPAEDIC SURGERY SPOONS AND CURETTES, REUSABLE
L0902 - ORTHOPAEDIC SURGERY LEVERS, REUSABLE
L090401 - ORTHOPAEDIC SURGERY OSTEOTOMES, REUSABLE
L090402 - ORTHOPAEDIC SURGERY SCALPELS, REUSABLE
L091201 - ORTHOPAEDIC SURGERY RASPS, REUSABLE
L091202 - ORTHOPAEDIC SURGERY FILES, REUSABLE
L091301 - BONE GRASPS, REUSABLE
L091305 - FORCEPS FOR TENDONS AND LIGAMENTS, REUSABLE
L091399 - ORTHOPAEDIC SURGERY FORCEPS, REUSABLE - OTHER
L0914 - SCOLLAPERIOSTIUM AND PERIOSTEOTOMES, REUSABLE
L0915 - SPREADERS AND RETRACTORS FOR ORTHOPAEDIC SURGERY, REUSABLE
L0916 - ORTHOPAEDIC SURGERY BURS AND TIPS, REUSABLE
L1104 - BITS FOR NEUROSURGERY DRILLS, REUSABLE
L110502 - NERVES AND VESSELS HOOK RETRACTORS, REUSABLE
L110601 - DISC HERNIA FORCEPS, REUSABLE
L1205 - LAPAROSCOPIC AND THORACOSCOPIC SURGERY NEEDLE HOLDERS, REUSABLE
L140101 - RHINOPHARYNGAL SURGERY INSTRUMENTS, REUSABLE
L140102 - OROPHARYNX SURGERY INSTRUMENTS, REUSABLE
L140204 - NASAL SURGERY RASPS AND FILES, REUSABLE
L140401 - TRACHEAL DILATORS, REUSABLE
L140602 - ENT CHISELS, REUSABLE
L149001 - ENT CURETTES, REUSABLE
L149002 - ENT LEVERS, REUSABLE
L149005 - ENT PROBES, REUSABLE
L1508 - REAMERS, REUSABLE
L170102 - OCULAR AND ENDOCULAR RETRACTORS, REUSABLE
L170299 - OPHTHALMOLOGY FORCEPS, REUSABLE - OTHER
L1703 - OPHTHALMOLOGY CURETTES, REUSABLE
U010199 - URETHRAL PROSTATIC AND BLADDER CATHETERS, NOT SELF-RETAINED - OTHER
V030201 - CALIPERS
Z120190 - VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY

Device Properties: MDS 1006 - Reusable surgical instruments

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

Revision History:

Rev.	Dated	Report	Description
00	2021-03-17	713179356	-
01	2023-05-03	713179356	Supplemented: Change to the approved type(s)/device(s)

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