



## 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](http://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  
 MDS 1006 - Reusable surgical instruments

**Device Properties:**



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

### 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)