



## 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. 00**

### Manufacturer:

**HEBUmedical GmbH**

Badstraße 8  
78532 Tuttlingen  
GERMANY

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. 00](http://www.tuvsud.com/ps-cert?q=cert:G11 049044 0017 Rev. 00)

### Report No.:

713179356

### Valid from:

2021-03-17

### Valid until:

2026-03-16

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2021-03-17



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**Classification:**

I

**Device Group:**

A019099 - NEEDLES - VARIOUS OTHER PROCEDURES  
A020299 - REUSABLE SYRINGES - OTHERS  
G020401 - HEMORRHOID LIGATURE SETS  
G030301 - POLYPECTOMY SNARES  
H030102 - SURGICAL CLIPS, OPEN-SURGERY  
L010101 - ONE-PIECE SCALPELS  
L010103 - SCALPEL HANDLES  
L0102 - SURGICAL KNIVES  
L0103 - DERMATOMES AND BLADES  
L010402 - SCISSORS, SUTURE  
L010403 - DISSECTING SCISSORS  
L010405 - SCISSORS, OPHTHALMIC  
L010406 - SCISSORS, ENT  
L010408 - SCISSORS, GASTRO-INTESTINAL  
L010409 - SCISSORS, THORACIC  
L010411 - SCISSORS, OBSTETRICS AND GYNAECOLOGY  
L010412 - SCISSORS, ORTHOPAEDIC  
L010413 - MICROSCISSORS  
L010499 - SURGICAL SCISSORS - OTHERS  
L0107 - SURGICAL SAWS  
L0202 - SUTURE NEEDLES  
L030199 - SURGICAL CANNULAS - OTHERS  
L031199 - PROBES AND STYLETS - OTHERS  
L0312 - TROCARS (not in category A)  
L031301 - BIOPSY FORCEPS, GENERAL SURGERY  
L031302 - FORCEPS, DRESSING  
L031303 - FORCEPS, SPONGE  
L031304 - FORCEPS, GRASPING  
L031309 - LIGATURES PASSERS  
L031310 - DISSECTING FORCEPS  
L031399 - FORCEPS, GENERAL SURGERY - OTHERS  
L031401 - RETRACTORS, GENERAL SURGERY  
L031402 - SPATULAE, GENERAL SURGERY  
L0315 - DISSECTORS, GENERAL SURGERY  
L040801 - SPECIALIZED FORCEPS, LIVER AND BILIARY TRACT  
L040802 - SPECIALIZED FORCEPS, GASTROINTESTINAL  
L040902 - RECTAL AND ANAL RETRACTORS  
L041002 - SURGICAL PROBES, DIGESTIVE SYSTEM  
L050901 - UTERINE CURETTES  
L050903 - FORCEPS, GYNAECOLOGICAL SURGERY  
L059001 - REUSABLE VAGINAL SPECULA  
L060502 - UROLOGICAL RETRACTORS  
L060601 - FORCEPS, KIDNEY  
L060603 - FORCEPS, MALE GENITALIA  
L070801 - FORCEPS, VASCULAR  
L080501 - FORCEPS, BRONCHUS  
L080502 - FORCEPS, LUNG  
L0901 - BONE SPOONS AND CURETTES  
L0902 - ELEVATORS, ORTHOPAEDIC SURGERY  
L090401 - OSTEOTOMES, ORTHOPAEDIC SURGERY



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L090402 - CHISELS, ORTHOPAEDIC SURGERY  
L091201 - RASPATORIES, ORTHOPAEDIC SURGERY  
L091202 - FILES, ORTHOPAEDIC SURGERY  
L091301 - GRASPING FORCEPS, BONE  
L091305 - FORCEPS, TENDONS AND LIGAMENTA  
L091399 - FORCEPS, ORTHOPAEDIC SURGERY - OTHERS  
L0914 - ORTHOPAEDIC ELEVATORS, PERIOSTEAL  
L0915 - ORTHOPAEDIC SURGERY DILATORS AND  
RETRACTORS  
L0916 - ORTHOPAEDIC BURS, REUSABLE  
L1104 - DRILLS AND BURS  
L110502 - NERVE/VESSEL HOOKS  
L110601 - INTERVERTEBRAL DISC RONGEURS  
L1205 - NEEDLE HOLDERS, MINI-INVASIVE SURGERY,  
REUSABLE  
L140101 - RHINOPHARYNX INSTRUMENTS  
L140102 - OROPHARYNX INSTRUMENTS  
L140204 - NASAL AND PARANASAL RASPATORIES AND FILES  
L140401 - TRACHEAL DILATORS  
L140602 - ENT CHISELS  
L149001 - ENT CURETTES  
L149002 - ENT ELEVATORS  
L149004 - ENT SPECULA, REUSABLE  
L149005 - ENT PROBES  
L1508 - REAMERS  
L160299 - DIAGNOSTIC MIRRORS - OTHERS  
L170102 - EYE RETRACTORS  
L170299 - FORCEPS, OPHTHALMIC - OTHERS  
L1703 - CURETTES, OPHTHALMIC  
U010199 - UROLOGICAL CATHETERS, NOT SELF-RETAINED -  
OTHERS  
V030201 - CALLIPERS  
V0399 - MEASUREMENT DEVICES - OTHERS  
Z120190 - VARIOUS INSTRUMENTS FOR GENERAL AND  
MULTIDISCIPLINARY SURGERY  
Z120206 - LOWER GASTROINTESTINAL TRACT ENDOSCOPY  
INSTRUMENTS  
Z121302 - ORTHOPEDIC TRACTION INSTRUMENTS

### Device Properties:

MDS 1006 - Reusable surgical instruments

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



# Certificate

No. Q5 049044 0015 Rev. 01

**Holder of Certificate:** **HEBUmedical GmbH**

Badstraße 8  
78532 Tuttlingen  
GERMANY

**Facility(ies):**

HEBUmedical GmbH  
Badstraße 8, 78532 Tuttlingen, GERMANY

See Scope below

**Certification Mark:**



**Scope of Certificate:**

**Design and Development, Production and Distribution of surgical instruments, oscillating saws, HF-Electrosurgical units, HF-Electrosurgical instruments and accessories and sterilization container**

**Applied Standard(s):**

EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 049044 0015 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5 049044 0015 Rev. 01)

**Report No.:** 713197851

**Valid from:** 2021-02-01

**Valid until:** 2024-01-31

**Date,** 2021-01-27

Christoph Dicks

Head of Certification/Notified Body

## Declaration of Quality

For our high-quality instruments we use only German Steel conforming to DIN 58298:2010-09 "Medical instruments-Materials, finish and testing", DIN EN ISO 13402 and EN ISO 7153-1:2002 "Surgical instruments - Metallic materials - Part 1: Stainless steel", whereby we fulfil even higher requirements than those stipulated in the standards by our own delimitation of the analysis values and the permissible structural condition.

By doing this, we improve the mechanical properties and the corrosion resistance of our instruments.

In our own material testing laboratory, equipped with the most modern testing equipment (chemical analysis, scanning electronic microscope, autoclave-test etc) we test and monitor every batch of raw material we receive, thus ensuring that only absolutely perfect material is employed in our production. We also guarantee a 100% traceability of each charge of raw material in case of any complains.

In detail we use the following materials in production:

Instrument	ISO Norm	Material acc. to German Industrial norm	Values in % acc. to Analyses	Hardness acc. to Rockwell Standards	USA Type AISI
All kind of Forceps, Needle Holders, Wound Retractors, Pliers	1.4021	X 20 Cr 13	C: 0,16-0,25 Cr: 12,0-14,0 Si: max. 1,0 Mn: max 1,5 S: max 0,015 P: max. 0,040	44-48	420
All kind of Scissors	1.4116	X 50 CrMoV 15	C: 0,45-0,55 Cr: 14,0-15,0 Mo: 0,50-0,80 V: 0,10-0,20 Si: max. 1,0 Mn: max. 1,0 S: max. 0,015 P: max. 0,040	52-58	-----
	1.4117	X38 CrMoV15	C: 0,35-0,40 Cr: 14,0-15,0 Mo: 0,40-0,60 V: 0,10-0,15 Si: max. 1,0 Mn: max. 1,0 S: max. 0,030 P: max. 0,045		
Raspatories, Chisels sharp, Dental Instruments, Roungeurs, Scalpel Handles	1.4034	X 46 CR 13	C: 0,43-0,50 Cr: 12,5-14,5 Si: max. 1,0 Mn: max 1,0 S: max. 0,015 P: max. 0,040	50-58	420C
Depressors, Vaginal Speculums, Maleable Instruments	1.4301	X 5 Cr Ni 18 10	Cr : 17,5-19,0 Ni : 8,0-10,5 C: max 0,07 Si: max 1,00 Mn: max 2,00 P: max 0,045 S: max 0,015	5-20	304

All instruments are passivated and all instruments are hardening and both process are validated.

All our instruments are UDI laser-marked according to the GS1 standard (supplier, item number , LOT number and Data matrix) and CE.

Tuttlingen, 30.08.2016



Thomas Butsch,

CEO, HEBUmedical GmbH, Germany

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Registergericht: AG Stuttgart HRB Nr. 450343