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. 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

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

Digitally signed by Cârstocea Ioan-Răzvan
Date: 2023.03.21 14:55:31 EET
Reason: MoldSign Signature
Location: Moldova

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TÜV SÜD
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No. G11 049044 0017 Rev. 00

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

No. G11 049044 0017 Rev. 00

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: ./.

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

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

Report No.: 713197851

Valid from: 2021-02-01
Valid until: 2024-01-31

Date, 2021-01-27

Christoph Dicks
Head of Certification/Notified Body

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