



EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 049044 0019 Rev. 00

Manufacturer: **HEBUmedical GmbH**
Badstraße 8
78532 Tuttlingen
GERMANY

SRN Manufacturer - DE-MF-000009286

The quality management system has been evaluated in accordance with Regulation (EU) 2017/745, Annex IX Chapter I with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.

The certified quality management system is subject to periodical surveillance.

If class I devices in sterile conditions, with measuring function, or reusable surgical instruments are covered by this certificate, the audit was limited to the respective 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.

If class IIa or class IIb devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.

If class III (excluding custom-made implantable devices) or class IIb implantable devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.

For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G15 049044 0019 Rev. 00

Report No.: 713380920
Preceding Certificate No.: G11 049044 0017 Rev. 01

Valid from: 2026-03-17
Valid until: 2031-03-16

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2026-01-28



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Classification:	Class I
Device Group:	A01 - NEEDLES G02 - GASTROINTESTINAL TUBES AND SETS H03 - HAEMOSTASIS CLIPS L01 - SHARP INSTRUMENTS, REUSABLE L02 - SUTURE INSTRUMENTS, REUSABLE L03 - GENERAL SURGERY INSTRUMENTS, REUSABLE L04 - ABDOMINAL SURGERY INSTRUMENTS, REUSABLE L05 - OBSTETRICS AND GYNECOLOGY INSTRUMENTS, REUSABLE L06 - UROLOGY INSTRUMENTS, REUSABLE L07 - CARDIOVASCULAR SURGERY INSTRUMENTS, REUSABLE L08 - THORACIC SURGERY INSTRUMENTS, REUSABLE L09 - ORTHOPAEDIC AND TRAUMATOLOGICAL SURGERY INSTRUMENTS, REUSABLE L11 - NEUROSURGERY AND SPINAL SURGERY INSTRUMENTS, REUSABLE L12 - LAPAROSCOPIC AND THORACOSCOPIC SURGERY INSTRUMENTS, REUSABLE L14 - ENT INSTRUMENTS, REUSABLE L15 - ODONTOSTOMATOLOGY INSTRUMENTS, REUSABLE L17 - OPHTHALMOLOGY INSTRUMENTS, REUSABLE V03 - MEASUREMENT DEVICES Z12 - INSTRUMENTS FOR FUNCTIONAL EXPLORATIONS AND THERAPEUTIC INTERVENTIONS
Device Properties:	MDS 1006 - Reusable surgical instruments

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

Revision History:

Rev.	Dated	Report	Description
00	2026-03-17	713380920	Renewal of certificate