CERTIFICADO ◆ 인증서 ◆ CERTIFICATO ◆ 認証書 ◆ CERTIFICATE ◆ 认证证书 ◆ ZERTIFIKAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

EU Quality Management System Certificate

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

Certificate No. G15 014101 0004 Rev. 01

Manufacturer:

Meyer-Haake GmbH Medical Innovations
Daimlerstraße 4
61239 Ober-Mörlen
GERMANY

SRN Manufacturer - DE-MF-000013583

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 014101 0004 Rev. 01

Report No.:	713347325
Preceding Certificate No.:	G15 014101 0004 Rev. 00
Valid from:	2026-11-06
Valid until:	2028-05-10
Date of Initial Issuance:	2025-08-01

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2026-11-06

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Certificate No. G15 014101 0004 Rev. 01

Classification:	Class IIb
Device Group:	K020399 - DEVICES FOR SURGERY WITH RADIOFREQUENCY GENERATOR, SINGLE-USE - OTHER
Intended Purpose:	High-frequency surgical device is used to cut and coagulate biological tissue by means of electrical energy. Used in operating theaters in medical practices and clinics. The use on the central nervous system, the central circulatory system and bones is excluded
Classification:	Class IIb
Device Group:	L180601 - OPEN ELECTROSURGERY ELECTRODES, REUSABLE
Intended Purpose:	Electrosurgical equipment for cutting and coagulating biological tissue by means of high-frequency electrical energy
The validity of this certificate depends on conditions and/or is limited to the following:	- none -

Revision History:

Rev.	Dated	Report	Description
00	2025-08-01	713338818	Initial issuance
01	2026-11-06	713347325	Supplemented: Device(s)/group of device(s) added

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