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

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

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

## Certificate No. G15 011655 0019 Rev. 00

**Manufacturer:** **Meditrade GmbH**
Medipark 1
83088 Kiefersfelden
GERMANY

SRN Manufacturer - DE-MF-000008937

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 011655 0019 Rev. 00

**Report No.:** 713334651
**Valid from:** 2025-12-15
**Valid until:** 2030-12-14

Christoph Dicks
Head of Certification/Notified Body

**Issue date:** 2025-12-15


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Heruntergeladen von Gast (IP 216.73.217.10) am 24.11.2026 um 14:06 Uhr · sana.swiss

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| | |
|---|---|
| **Classification:** | Class I |
| **Device Group:** | T010202 - SYNTHETIC EXAMINATION / TREATMENT GLOVES<br>T01020299 - SYNTHETIC EXAMINATION / TREATMENT GLOVES - OTHER |
| **Device Properties:** | MDS 1005 - Devices in sterile condition |
| **The validity of this certificate depends on conditions and/or is limited to the following:** | - |

**Revision History:**

| Rev. | Dated | Report | Description |
|---|---|---|---|
| 00 | 2025-12-15 | 713334651 | Initial issuance |



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