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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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BS-MDR-099

Product Service

# EU Quality Management System Certificate

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

## Certificate No. G15 002145 0007 Rev. 00

**Manufacturer:**

**Shenzhen IMDK Medical Technology CO., Ltd**
904, 9F
Guangming Tianan Cloud Park Building
255 Zhenmei Road, Zhenmei Community
Xinhu Street
Guangming District
518107 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000024290

**Authorized Representative:**

MedNet EC-REP GmbH
Borkstraße 10, 48163 Münster, GERMANY

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 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 002145 0007 Rev. 00

**Report No.:** GZ2428303
**Preceding Certificate No.:** G10 002145 0004 Rev. 00

**Valid from:** 2025-10-22
**Valid until:** 2028-11-23

**Issue date:** 2025-10-22

Christoph Dicks
Head of Certification/Notified Body


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| | |
|---|---|
| **Classification:** | Class IIa |
| **Device Group:** | MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters |
| **Classification:** | Class IIa |
| **Device Group:** | MDA 0307 - Active non-implantable respiratory devices |
| **Classification:** | Class IIa |
| **Device Group:** | MDN 1201 - Non-active non-implantable devices for anaesthesia, emergency and intensive care |
| **The validity of this certificate depends on conditions and/or is limited to the following:** | -none- |

**Revision History:**

| Rev. | Dated | Report | Description |
|---|---|---|---|
| 00 | 2025-10-22 | GZ2428303 | Supplemented: Device(s)/group of device(s) added<br>Administrative merge / transfer to new Certificate Type |



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