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

Product Service

# EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

## No. G21 002037 0015 Rev. 02

**Manufacturer:**

**Allmed Medical Products Co., Ltd**
No.18 Qixing Road, Majiadian Town
443200 Zhijiang City, Hubei Province
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000007970

**Authorized Representative:**

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, 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 XI Part A 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 assurance system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. 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:G21 002037 0015 Rev. 02

**Report No.:** SH25025601

**Preceding Certificate No.:** G21 002037 0015 Rev. 01

**Valid from:** 2025-08-12
**Valid until:** 2028-07-09

**Date of Initial Issuance:** 2023-07-10

**Issue date:** 2025-08-12

Christoph Dicks
Head of Certification/Notified Body


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

## No. G21 002037 0015 Rev. 02

| | |
|---|---|
| **Classification:** | Class I |
| **Device Group:** | V01 - CUTTING DEVICES, SINGLE-USE |
| **Device Properties:** | MDS 1005.1 - Ethylene Oxide sterilization |

| | |
|---|---|
| **Classification:** | Class I |
| **Device Group:** | M01 - COTTON AND SYNTHETIC WADDING |
| **Device Properties:** | MDS 1005.1 - Ethylene Oxide sterilization |

| | |
|---|---|
| **Classification:** | Class I |
| **Device Group:** | M02 - GAUZES |
| **Device Properties:** | MDS 1005.1 - Ethylene Oxide sterilization<br>MDS 1005.3 - Sterilization by moist heat |

| | |
|---|---|
| **Classification:** | Class I |
| **Device Group:** | M03 - BANDAGES |
| **Device Properties:** | MDS 1005.1 - Ethylene Oxide sterilization |

| | |
|---|---|
| **Classification:** | Class I |
| **Device Group:** | M04 - SPECIAL DRESSINGS |
| **Device Properties:** | MDS 1005.1 - Ethylene Oxide sterilization<br>MDS 1005.2 - Sterilization by irradiation<br>MDS 1005.3 - Sterilization by moist heat |

| | |
|---|---|
| **Classification:** | Class I |
| **Device Group:** | T01 - GLOVES (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT - PPE) |
| **Device Properties:** | MDS 1005.1 - Ethylene Oxide sterilization |

| | |
|---|---|
| **Classification:** | Class I |
| **Device Group:** | T02 - PROTECTIVE CLOTHING AND DRAPES (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT - PPE) |
| **Device Properties:** | MDS 1005.1 - Ethylene Oxide sterilization |

| | |
|---|---|
| **Classification:** | Class I |
| **Device Group:** | T04 - INCONTINENCE DEVICES |
| **Device Properties:** | MDS 1005.1 - Ethylene Oxide sterilization |

| | |
|---|---|
| **Classification:** | Class I |
| **Device Group:** | V90 - VARIOUS DEVICES NOT INCLUDED IN OTHER CLASSES |
| **Device Properties:** | MDS 1005.1 - Ethylene Oxide sterilization |


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

## No. G21 002037 0015 Rev. 02

| | |
|---|---|
| **Classification:** | Class I |
| **Device Group:** | V04 - CLINICAL USE CONTAINERS (NON-IVD) |
| **Device Properties:** | MDS 1005.1 - Ethylene Oxide sterilization |

| | |
|---|---|
| **Classification:** | Class I |
| **Device Group:** | V02 - NEONATOLOGY AND PAEDIATRIC DEVICES |
| **Device Properties:** | MDS 1005.1 - Ethylene Oxide sterilization |

| | |
|---|---|
| **Classification:** | Class I |
| **Device Group:** | V05 - CLINICAL PROCEDURES KITS NOT INCLUDED IN OTHER CLASSES |
| **Device Properties:** | MDS 1005.1 - Ethylene Oxide sterilization |

**The validity of this certificate depends on conditions and/or is limited to the following:** /

**Revision History:**

| Rev. | Dated | Report | Description |
|---|---|---|---|
| 00 | 2023-07-10 | SH2125602 | Initial issuance |
| 01 | 2025-03-19 | SH2425601 | Supplemented: Device(s)/group of device(s) added |
| 02 | 2025-08-12 | SH25025601 | Supplemented: Device(s)/group of device(s) added |


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