



# Certificate

No. Q8 002037 0002 Rev. 02

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

**Certification Mark:**



**Scope of Certificate:** **Sterilization of Medical Devices**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:  
[www.tuvsud.com/ps-cert?q=cert:Q8 002037 0002 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q8_002037_0002_Rev_02)

**Report No.:** SH2025601

**Valid from:** 2020-08-28

**Valid until:** 2022-08-31

**Date,** 2020-08-28

Christoph Dicks  
Head of Certification/Notified Body

# Certificate

No. Q8 002037 0002 Rev. 02

## Applied Standard(s):

EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

## Facility(ies):

Allmed Medical Products Co., Ltd.  
No. 180 Gong Yuan Road, Majiadian Town, 443200 Zhijiang City,  
Hubei Province, PEOPLE'S REPUBLIC OF CHINA

Allmed Medical Products Co., Ltd.  
No. 76, You Yi Road, Majiadian Town, 443200 Zhijiang City, Hubei  
Province, PEOPLE'S REPUBLIC OF CHINA

Allmed Medical Products Co., Ltd.  
No. 99, Jin Shan Road, Majiadian Town, 443200 Zhijiang City,  
Hubei Province, PEOPLE'S REPUBLIC OF CHINA

Allmed Medical Products Co., Ltd.-Jianli  
No.168-1(Te), Yusha Road, Rongcheng Town, Jianli County,  
433300 Jingzhou, Hubei, PEOPLE'S REPUBLIC OF CHINA



Product Service

# Supplement to Quality System Certificate

No. SUP 002037 0011 Rev. 01

This supplement is  
only valid in  
conjunction with the  
main certificate:

**Q8 002037 0002 Rev. 02**

**Certificate Holder:**

**Allmed Medical Products Co., Ltd**

No.18 Qixing Road, Majiadian Town  
443200 Zhijiang City, Hubei Province  
PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):**

Allmed Medical Products Co., Ltd.

No. 99, Jin Shan Road, Majiadian Town, 443200 Zhijiang  
City, Hubei Province, PEOPLE'S REPUBLIC OF CHINA

Allmed Medical Products Co., Ltd.-Jianli

No.168-1(Te), Yusha Road, Rongcheng Town, Jianli County,  
433300 Jingzhou, Hubei, PEOPLE'S REPUBLIC OF CHINA

The quality system certified as stated in the main certificate additionally fulfills the applicable requirements of

EN ISO 11135:2014 "Sterilization of health-care products -  
Ethylene oxide - Requirements for the development,  
validation and routine control of a sterilization process for  
medical devices (ISO 11135:2014)"

**Audit Report:**

SH2025601

**Dated:**

2020-08-08

The assessment was performed by auditors authorized under TÜV SÜD Product Service GmbH procedures. The audit team included an auditor authorized for sterilization

**Valid from:**

2020-08-28

Christoph Dicks

Head of Certification/Notified Body



# Supplement to Quality System Certificate

No. SUP 002037 0012 Rev. 01

This supplement is  
only valid in  
conjunction with the  
main certificate:

**Q8 002037 0002 Rev. 02**

**Certificate Holder:**

**Allmed Medical Products Co., Ltd**

No.18 Qixing Road, Majiadian Town  
443200 Zhijiang City, Hubei Province  
PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):**

Allmed Medical Products Co., Ltd.  
No. 180 Gong Yuan Road, Majiadian Town, 443200 Zhijiang  
City, Hubei Province, PEOPLE'S REPUBLIC OF CHINA

Allmed Medical Products Co., Ltd.  
No. 76, You Yi Road, Majiadian Town, 443200 Zhijiang City,  
Hubei Province, PEOPLE'S REPUBLIC OF CHINA

Allmed Medical Products Co., Ltd.-Jianli  
No.168-1(Te), Yusha Road, Rongcheng Town, Jianli County,  
433300 Jingzhou, Hubei, PEOPLE'S REPUBLIC OF CHINA

The quality system certified as stated in the main certificate additionally fulfills the applicable requirements of

EN ISO 17665-1:2006 "Sterilization of health care products –  
Moist heat – Part 1: Requirements for the development,  
validation and routine control of a sterilization process for  
medical devices (ISO 17665-1:2006)"

**Audit Report:**

SH2025601

**Dated:**

2020-08-08

The assessment was performed by auditors authorized under TÜV SÜD Product Service GmbH procedures. The audit team included an auditor authorized for sterilization

**Valid from:**

2020-08-28



Christoph Dicks  
Head of Certification/Notified Body