



# Certificate

No. Q8 004593 0005 Rev. 00

**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):** Shenzhen Antmed Co., Ltd.  
18 Jinhui Ave., Pingshan New District, 518122 Shenzhen,  
PEOPLE'S REPUBLIC OF CHINA

Shenzhen Antmed Co., Ltd.  
46 Keji Ave., Yuquan Industrial Park, Fenggang, 523696  
Dongguan, PEOPLE'S REPUBLIC OF CHINA

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Product Service

## Supplement to Quality System Certificate

No. SUP 004593 0006 Rev. 00

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

**Q8 004593 0005 Rev. 00**

**Certificate Holder:**

**Shenzhen Antmed Co., Ltd.**

18 Jinhui Ave., Pingshan New District  
518122 Shenzhen  
PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):**

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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:**

BJ19811031

**Dated:**

2019-06-20

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:**

2020-02-20

Christoph Dicks  
Head of Certification/Notified Body