A4 / 07.17







Certificate No. Q8 004593 0005 Rev. 00

Holder of Certificate:

Shenzhen Antmed Co., Ltd. 18 Jinhui Ave., Pingshan New District 518122 Shenzhen

PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Provision of ETO Sterilization Service for Single used Medical Device.

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). See also notes overleaf.

Report No.:

BJ19811031

Valid from: Valid until: 2020-02-20 2020-10-30

Date,

2020-02-20

Christoph Dicks Head of Certification/Notified Body

A4 / 07.17

.





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



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):	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
The quality system certified as st requirements of	ated in the main certificate additionally fulfills the applicable 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: Dated:	BJ19811031 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
	C.Dr

Christoph Dicks Head of Certification/Notified Body