



America

CERTIFICATE

No. QS6 004593 0008 Rev. 00

Certificate Holder:

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

Certification Mark:



Scope of Certificate:

Design and Development, Production, Distribution, and Servicing of Injection Tubing System, High Pressure Syringe, Pressure Connecting Tube, Disposable Pressure Transducer for the areas of Radiology, Anesthesiology, Cardiovascular Application

Standard(s):

ISO 13485:2016

Regulatory Authority(ies):

Australia TGA, Brazil ANVISA, Health Canada, USA FDA.
See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website <https://www.tuev-sued.de/product-testing/certificates>

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No:

52-722-1254

Effective Date:

2019-08-13

Expiry Date:

2022-08-12

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Date of Issue: 2019-10-16

(Dawn M. Tibodeau)
Manager, Certification Body MHS

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Regulatory Requirements: Audit/Certification Criteria

Australia

- Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

Brazil

- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada

- Medical Device Regulations SOR/98-282, Part 1

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

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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Facility Scopes:

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

Management and Regulatory Affair of Injection Tubing
System, High Pressure Syringe, Pressure Connecting
Tube, Disposable Pressure Transducer for the areas
of Radiology, Anesthesiology, Cardiovascular Application
DUNS No: 52-722-1254

Shenzhen Antmed Co., Ltd.

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

Design and Development, Production, Distribution, and
Servicing of Injection Tubing System, High Pressure
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DUNS No: 54-842-0851

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