MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD 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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(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

Date of Issue: 2019-10-16

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Facility Scopes:

Shenzhen Antmed Co., Ltd.
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 Syringe, Pressure Connecting Tube, Disposable Pressure Transducer for the areas of Radiology, Anesthesiology, Cardiovascular Application
DUNS No: 54-842-0851

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