HIGH PRESSURE SYRINGE

P/N: 300102

Compatible with Nemoto A60, A300 Injector

Contents: 1-200ml Syringe
1-150cm CT Coiled Tube
1-Quick Fill Tube

Packing: 50PCS/CASE

Digitally signed by Volcovschi Mihai
Date: 2026.05.22 10:50:36 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

FDA 510(K)

CE 0123

antmed
Partner For Life

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 004593 0004 Rev. 07

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

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Production, Sales and Distribution of High Pressure Syringe, Control Syringe, Color Syringe, Bladder Catheter Valve, Manifold, Pressure Connecting Tube, Hemostasis Valve, Introducer Set, Inflation Device, Positive Needlefree Connector, Disposable Pressure Transducer, Disposable Pressure Transducer Kit, Manifold Kit, PTCA Kit, Injection Tubing System, I.V Catheter for Single Use, Filling Device, Adaptor for High Pressure Syringe, Multi-Patient Syringe System, Contrast Media Injectors, Transfer Set.**

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, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 004593 0004 Rev. 07

Report No.: BJ24081103

Valid from: 2024-10-08
Valid until: 2026-10-30

Date, 2024-10-08

Christoph Dicks
Head of Certification/Notified Body

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 004593 0004 Rev. 07

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

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

The Provision of Management Services for High Pressure Syringe, Control Syringe, Color Syringe, Bladder Catheter Valve, Manifold, Pressure Connecting Tube, Hemostasis Valve, Introducer Set, Inflation Device, Positive Needlefree Connector, Disposable Pressure Transducer, Disposable Pressure Transducer Kit, Manifold Kit, PTCA Kit, Injection Tubing System, I.V Catheter for Single Use, Filling Device, Adaptor for High Pressure Syringe, Multi-Patient Syringe System, Contrast Media Injectors, Transfer Set.

Shenzhen Antmed Co., Ltd.
No.3 Hualian Ave, Songshanhu District, 523800 Dongguan, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production, Sales and Distribution of High Pressure Syringe, Control Syringe, Color Syringe, Bladder Catheter Valve, Manifold, Pressure Connecting Tube, Hemostasis Valve, Introducer Set, Inflation Device, Positive Needlefree Connector, Disposable Pressure Transducer, Disposable Pressure Transducer Kit, Manifold Kit, PTCA Kit, Injection Tubing System, I.V Catheter for Single Use, Filling Device, Adaptor for High Pressure Syringe, Multi-Patient Syringe System, Contrast Media Injectors, Transfer Set.

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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 004593 0011 Rev. 00

Manufacturer:

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

SRN Manufacturer - CN-MF-000029659

Authorized Representative:

MedNet EC-REP C IIb GmbH
Borkstrasse 10, 48163 Münster, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
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:G10 004593 0011 Rev. 00

Report No.: BJ23081103

Valid from: 2024-02-06
Valid until: 2029-02-05

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-02-06

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BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 004593 0011 Rev. 00

Classification:	Class IIa
Device Group:	A020102 - INFUSION AND IRRIGATION SYRINGES, SINGLE-USE
Intended Purpose:	-
Classification:	Class IIa
Device Group:	A030201 - EXTENSIONS
Intended Purpose:	-
Classification:	Class IIa
Device Group:	A030401 - INFUSION KITS (INCLUDING THOSE VIA PUMP), SINGLE-USE
Intended Purpose:	-
Classification:	Class IIb
Device Group:	Z120302 - VITAL SIGNS MONITORING INSTRUMENTS
Intended Purpose:	The product is used for monitoring the arterial pressure and central venous pressure of patients, and in conjunction with a patient monitor with invasive blood pressure monitoring function.
The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Revision History:

Rev.	Dated	Report	Description
00	2024-02-06	BJ23081103	Initial issuance

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Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

G11 004593 0012 Rev. 00

Manufacturer:

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

SRN Manufacturer - CN-MF-000029659

Authorized Representative:

MedNet EC-REP C IIb GmbH
Borkstrasse 10, 48163 Münster, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. As applicable the involvement of the notified body is limited to the aspects relating to:
- establishing, securing and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. 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:G11 004593 0012 Rev. 00 0012 Rev. 00

Report No.: BJ23081103

Valid from: 2024-02-06
Valid until: 2029-02-05

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-02-06

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BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

G11 004593 0012 Rev. 00

Classification:	Class I
Device Group:	A020102 - INFUSION AND IRRIGATION SYRINGES, SINGLE-USE
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization MDS 1010 - Devices with a measuring function

Classification:	Class I
Device Group:	A030201 - EXTENSIONS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

Classification:	Class I
Device Group:	C010401 - CARDIAC ANGIOGRAPHY DEVICES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization MDS 1010 - Devices with a measuring function

Classification:	Class I
Device Group:	C900101 - HAEMOSTASIS VALVES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

The validity of this certificate depends on conditions and/or is limited to the following:	-None-

Revision History:

Rev.	Dated	Report	Description
00	2024-02-06	BJ23081103	Initial issuance

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