

# HIGH PRESSURE SYRINGE



**P/N: 300101**

**Compatible with Nemoto A60, A300, Smart Shot Alpha Injector**

**Contents: 1-100ml Syringe  
1-150cm CT Coiled Tube  
1-Quick Fill Tube  
1-Long Spike**

**Packing: 50PCS/CASE**



**antmed**  
Partner For Life



## 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](http://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



## 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



## 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](http://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



## 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



# 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:**



**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](http://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

# 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.