# HIGH PRESSURE SYRINGE



**Compatible with Nemoto Dual Shot Injector** 

**Contents: 1-100ml Syringe** 

1-200ml Syringe

1-150cm CT Coiled U Tube with dual check valves

1-Quick Fill Tube

1-Long Spike

Packing: 20PCS/CASE













Product Service

### **EC** Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 004593 0002 Rev. 01

Manufacturer: Shenzhen Antmed Co., Ltd.

18 Jinhui Ave., Pingshan New District

518122 Shenzhen

PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): High Pressure Syringe, Manifold, Pressure

Connecting Tube, Introducer Set, Disposable Pressure Transducer. Positive Needlefree

Connector, Disposable Pressure Transducer Kit, Manifold Kit, PTCA Kit, Injection Tubing System, I.V.catheter for Single Use, Filling Device, Multi-

Patient Syringe System, Contrast Media Injectors.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final

assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

inspection of the respective devices / device categories in accordance with MDD Annex II. This quality

Report No.: BJ1981107

 Valid from:
 2020-02-25

 Valid until:
 2024-05-26

Date, 2020-02-25

Christoph Dicks

Head of Certification/Notified Body



### **EC** Certificate

Full Quality Assurance System Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) (Devices in Class IIa, IIb or III)

No. G1 004593 0002 Rev. 01

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







#### **Product Service**

### **Certificate**

No. Q5 004593 0004 Rev. 03

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.

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 and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: <a href="https://www.tuvsud.com/ps-cert?q=cert:Q5">www.tuvsud.com/ps-cert:Q5</a> 004593 0004 Rev. 03

**Report No.:** BJ20081102 2

 Valid from:
 2021-05-01

 Valid until:
 2023-10-30

Date. 2021-04-07 Christoph Dicks

Head of Certification/Notified Body





## **Certificate**

No. Q5 004593 0004 Rev. 03

EN ISO 13485:2016 Applied Standard(s):

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

Shenzhen Antmed Co., Ltd. Facility(ies):

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.

Shenzhen Antmed Co., Ltd.

46 Keji Ave., Yuguan Industrial Park, Fenggang, 523696

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.

