

HIGH PRESSURE SYRINGE



P/N: 100110

Compatible with Medrad/Bayer Stellant Dual head Injector

Contents: 2-200ml Syringes

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

2-Long Spikes

Packing: 20PCS/CASE



antmed
Partner For Life

Pressure Connecting Tube



P/N: 600104

Length: 150cm

Pressure: 350PSI

Description: 150cm CT Coiled U Tube with Dual Check Valves

Used for CT dual head injection system

Packing: 200PCS/CASE



antmed
Partner For Life



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



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

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



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: www.tuvsud.com/ps-cert?q=cert:Q5 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

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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.

Shenzhen Antmed Co., Ltd.
46 Keji Ave., Yuquan 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.