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

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

A4 / 07.17

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

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

.

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV®