ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 16 12 56846 025

Manufacturer:

Shenzhen Ant Hi-Tech Industrial Co., Ltd.
18 Jinhui Ave., Pingshan New District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

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, Sterile Intravenous needles for single use, Multi-Patient Syringe System.

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.: BJ1681104

Valid from: 2017-05-02
Valid until: 2020-11-15

Date, 2017-05-02

Stefan Preiß

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

TÜV®

A1 / 04.11

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 16 12 56846 025

Facility(ies):

Shenzhen Ant Hi-Tech Industrial Co., Ltd.
18 Jinhui Ave., Pingshan New District, 518122 Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

Shenzhen Ant Hi-Tech Industrial Co., Ltd.
46 Keji Ave., Yuquan Industrial Park, Fenggang, 523696
Dongguan, PEOPLE'S REPUBLIC OF CHINA

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®