



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 15 07 56846 023

**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, Sterile Intravenous needles for single use, Filling Device.

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.:** BJ1581107

**Valid from:** 2015-11-16

**Valid until:** 2020-11-15

**Date,** 2015-09-07

Hans-Heiner Junker

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

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#### 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