



Product Service

# EC Certificate

## Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V  
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 15 07 56846 024

**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):** Control Syringe, Color Syringe, Bladder Catheter Valve, Hemostasis Valve, Inflation Device.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. 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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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