



Product Service

CERTIFICATE

No. Q1N 17 08 56846 027

Holder of Certificate: Shenzhen Ant Hi-Tech Industrial Co., Ltd.

18 Jinhui Ave., Pingshan New District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

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



Certification Mark:



Scope of Certificate:

Design, 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, Sterile Intravenous needles for single use, Filling Device, Adaptor for high pressure syringe, Multi-patient Syringe System.

Applied Standard(s):

EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012
Upgrade required until 2019-03-31

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). See also notes overleaf.

Report No.: BJ1781104
Valid from: 2017-12-08
Valid until: 2020-10-30

Date, 2017-12-08

Stefan Preiß



Page 1 of 1

