DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q6 050079 0013 Rev. 00

Holder of Certificate: **Shenzhen Ant Medical Devices Co., Ltd.**
18 Jinhui Ave., Pingshan New District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Shenzhen Ant Medical Devices Co., Ltd.
18 Jinhui Ave., Pingshan New District, 518122 Shenzhen.
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Production, Sales and Distribution of High Pressure Syringe, Pressure Connecting Tube, and Injection Tubing System.**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: BJ18899041

Valid from: 2018-09-01
Valid until: 2021-08-31

Date, 2018-08-28

Stefan Preiß

Digitally signed by Iarovoi Petru
Date: 2019.02.01 16:45:36 EET
Reason: MoldSign Signature
Location: Moldova

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 050079 0012 Rev. 01

Manufacturer:	**Shenzhen Ant Medical Devices 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, Pressure Connecting Tube, Injection Tubing System.**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.:	BJ1889907
Valid from:	2018-09-18
Valid until:	2023-09-17

Date, 2018-08-07

Stefan Preiß

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Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 050079 0012 Rev. 01

Facility(ies):

Shenzhen Ant Medical Devices Co., Ltd.
18 Jinhui Ave., Pingshan New District, 518122 Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

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

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