





Product Service

Certificate

No. Q5 003321 0003 Rev. 03

Holder of Certificate: Shenzhen MicroApproach

Medical Technology Co., Ltd.

Room 705, No.1 Building

Shenzhen Biomedical Innovation Industrial Park

No.14 Jinhui Road, Kengzi Street

Pingshan Distrct 518122 Shenzhen

PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: Design and Development, Production and

Distribution of Guide wire hydrophilic coating, Zebra guide wire, Angiographic

catheter, Guiding catheter, Sheath

introducer, Micro catheter, Ureteral stent kit

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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 003321 0003 Rev. 03

Report No.: GZ2132901

 Valid from:
 2021-09-22

 Valid until:
 2024-09-21

Date, 2021-09-22 Christoph Dicks

Head of Certification/Notified Body



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EN ISO 13485:2016 **Applied Standard(s):**

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

Facility(ies): Shenzhen MicroApproach Medical Technology Co., Ltd.

Room 705, No.1 Building, Shenzhen Biomedical Innovation Industrial Park, No.14 Jinhui Road, Kengzi Street, Pingshan Distrct, 518122 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate