



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

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 003321 0004 Rev. 03

Manufacturer:

**Shenzhen MicroApproach
Medical Technology Co., Ltd.**

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

Product Category(ies): 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 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. 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:G10033210004Rev.03

Report No.: GZ2032902

Valid from: 2021-02-23

Valid until: 2023-08-02

Date, 2021-02-23

Christoph Dicks
Head of Certification/Notified Body



Certificate

No. Q5 003321 0003 Rev. 05

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 District
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, Urological hydrophilic guidewire, PTCA guidewire, Extra-Stiff guidewire, Neuro micro guidewire, Control guidewire, Hydrophilic angiographic catheter, Micro catheter kit, CTO guidewire, Y connector set, Micro guidewire.**

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. 05

Report No.: GZ2332902

Valid from: 2023-07-31

Valid until: 2024-09-21

Date, 2023-07-31

Christoph Dicks

Head of Certification/Notified Body

Certificate

No. Q5 003321 0003 Rev. 05

Applied Standard(s):

EN ISO 13485:2016
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 District, 518122 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

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, Urological hydrophilic guidewire, PTCA guidewire, Extra-Stiff guidewire, Neuro micro guidewire, Control guidewire, Hydrophilic angiographic catheter, Micro catheter kit, CTO guidewire, Y connector set, Micro guidewire.

Shenzhen MicroApproach Medical Technology Co., Ltd.

Room 101, No.3 Workshop and Room 301, No.4 Workshop, No.14 Zhongxing Road, Kengzi Street, Pingshan District, 518122 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Production of Guide wire hydrophilic coating, Zebra guide wire, Angiographic catheter, Guiding catheter, Sheath introducer, Micro catheter, Ureteral stent kit, Urological hydrophilic guidewire, PTCA guidewire, Extra-Stiff guidewire, Neuro micro guidewire, Control guidewire, Hydrophilic angiographic catheter, Micro catheter kit, CTO guidewire, Y connector set, Micro guidewire.