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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD 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 Distrct
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:G1 003321 0004 Rev. 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

Digitally signed by Perminov Andrei
Date: 2022.03.14 09:36:09 EET
Reason: MoldSign Signature
Location: Moldova

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

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

TÜV®

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

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

TÜV SÜD 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:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

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

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

TÜV®

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

TÜV SÜD
Product Service

Certificate

No. Q5 003321 0003 Rev. 03

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 Distrct, 518122 Shenzhen, PEOPLE'S REPUBLIC OF CHINA**

See Scope of Certificate

.

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

TÜV®