



Certificate

No. Q5 104068 0001 Rev. 02

Holder of Certificate: **SCW Medicath Ltd.**
No.4, Baolong 6th Road
Baolong Industrial Town
Longgang District
518116 Shenzhen, Guangdong
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: Design and Development, Production and Distribution of Hydrophilic Guidewire, Peripheral Angiographic Catheter, Guiding Catheter, Hemostasis Valve Set, Balloon Inflation Device, Dose-control Syringe, Colored piston specialty Syringe, Pressure Bandage, Disposable Pressure Transducer, Introducer Set, Guide Wire, Connecting Tubing, Stopcock, Angiographic Syringe, Manifold, Introducer Needle, Manifold Set, Peelable Introducer Set, Postpartum Balloon, Cervical Ripening Balloon, Percutaneous Access Set, ERCP Guidewire, Percutaneous Nephrostomy Set, Hydrophilic Introducer Set, Balloon Uterine Stent, Microcatheter, Ureteral Access Sheath, Bone Cement Mixer, Central Venous Catheter Kit, Haemodialysis Catheter Kit, PTCA Balloon Catheter, Arterial Cannula, Endometrial Sampling Brush, Bone Access Kit, Stone Extractor, Stone Extraction Catheter, Drainage Catheter Set, Ureteral Stent Set, Locking Drainage Catheter, Tracheostomy Tube 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 104068 0001 Rev. 02

Report No.: GZ2242701

Valid from: 2023-01-07
Valid until: 2026-01-06

Date, 2022-12-29

Christoph Dicks
Head of Certification/Notified Body

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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):

SCW Medicath Ltd.
No.4, Baolong 6th Road, Baolong Industrial Town, Longgang
District, 518116 Shenzhen, Guangdong, PEOPLE'S REPUBLIC
OF CHINA

See Scope of Certificate