

# Certificate



## Quality Management System EN ISO 13485:2016

Registration No.: SX 2095157-1

Organization: SCW MedicaTh Ltd.  
No. 4, Baolong 6th Road, Baolong  
Industrial Town, Longgang District  
Shenzhen  
518116 Guangdong  
P.R. China

Scope: Design and Development, Manufacture and Distribution of Disposable Pressure Transducers, Introducer Sets, Guide Wires, Angiographic Syringes, Hemodialysis Catheterization Kits, Patient-Controlled Analgesic Infusion Pumps, Disposable Infusion Pumps, Tracheostomy Tube Kits, Percutaneous Nephrostomy Sets, Ureteral Stent Sets, Drainage Catheter Sets, Transradial Introducer Sets, Introducer Needles, I.V Cannulas, Cervical Ripening Balloon, Postpartum Balloon, Manifolds, Stopcocks, Manifold Sets, Connecting Tubings, Dose-control Syringes, Balloon Inflation Devices, Colored Piston Specialty Syringes, Infusion Sets with Needleless Adapters, Pressure Bandages, Hemostasis Valve Sets, Locking Drainage Catheters, Percutaneous Access Sets, ERCP Guidewires, Injection Caps

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

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Dipl.-Ing. W. Hsu

TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany



Deutsche  
Akkreditierungsstelle  
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