

Certificate



**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 2064548-1

Organization: COPPER MEDICAL TECHNOLOGY
CO., LTD.
Factory Building B1 (101-201),
Glory Industrial Factory Zone,
No.2 Baolong 5 Road,
Longgang Shenzhen
518116 Guangdong
P.R. China

Scope: Design and Development, Manufacture and Distribution of Percutaneous Nephrostomy Sets, Ureteral Stent Sets, Introducer Sets, Hemostasis Valve Sets, Balloon Inflation Devices, Dose-Control Syringes, Disposable Pressure Transducers, Angiographic Syringes, Drainage Catheter Sets, Ureteral Access Sheaths, Guide Wires, Bladder Irrigators;
Provision of Ethylene Oxygen Sterilization Service in accordance with EN ISO 11135:2014

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.

Report No.: 10918811-100
Effective date: 2021-12-21
Expiry date: 2024-12-20
Issue date: 2021-12-21





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