Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.:	SX 2008073-1
Certificate Holder:	Shandong Hapool Medical Technology Co., Ltd. J5 # -C Zone Zibo Comprehensive Free Trade Zone, High-tech Zone, Zibo City, 255000 Shandong, P.R. China
Scope:	Design and Development, Manufacture and Distribution of Scalp Vein Sets, Three-way Stopcocks, Disposable Syringe with Needles, Infusion Sets, Insulin Syringes, Medical Examination Gloves, Sterile Urine Drainage Bags, I.V. Flow Regulators, Needle Free Connectors, Intravenous Infusion Sets with Burette, Blood Transfusion Sets, Non-woven Face Masks, Non-woven Coveralls, Sterile Latex Surgical Gloves

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.:	190160795-110
Effective date:	2025-01-17
Expiry date:	2028-01-16
Issue date:	2025-01-09

Replaces certificate SX 2008073-1 issued 2023-07-06

This certificate can be validated on https://www.certipedia.com

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