

Certificate

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

Registration No.: SX 2074202-1

Certificate Holder: Rizhao Sanqi Medical & Health Articles Co., Ltd.
No.137, Rizhao North Road, High-tech Zone,
Rizhao, 276800 Shandong, P.R. China

Scope: Design and Development, Manufacture and Distribution of
Face Masks for Medical Use, Caps for Medical Use, Gowns
for Medical Use, Shoe Covers for Medical Use, Boot Covers
for Medical Use, Sleeve Covers for Medical Use, Medical Bed
Sheets, Surgical Drapes, Surgical Sheets, Medical Non-woven
Fabric Sheets, Medical Pillow Covers, Operating Theater
Sheets, Dressing Kits for Medical Use, Surgical Packs,
Obstetric Kits, Nursing Kits, Disposable Surgical Intervention
Packs, Dental Kits, Gynecology Kits, Surgical Operating
Instrument Kits, Dental Aprons, Dental Shawls, Medical
Gauzes, Dental Cotton Rolls, Medical Cotton Swabs, Medical
Splash Shields, Safety Goggles for Medical Use, Isolation
Gowns, Lab Coats for Medical Use, Surgical Gowns, Medical
Disposable Protective Clothing, Medical Examination Gloves
(Nitrile Gloves, Latex Gloves, PE Gloves, PVC Gloves),
Medical Wipes, Medical Underpads, Adult Diapers, Medical
Disposable Tourniquets, Medical Tourniquets with Buckles,
Medical Bandages, Anesthesia Mask Straps for Medical Use,
Bite Blocks for Medical Use (with strap);
Provision of Ethylene Oxide Sterilization Service for Single-use
Medical Devices 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.: 190172426-110

Effective date: 2026-02-28

Expiry date: 2029-02-27

Issue date: 2026-02-02

Replaces certificate SX 2074202-1 issued 2025-03-17

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


Yuhong Chen

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