

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 2163833-1

Certificate Holder: Changzhou Yuekang Medical Appliance Co., Ltd.
No. 2 Meijia Village,
Jiaoxi, Zhenglu Town, Tianning District,
Changzhou
213116 Jiangsu
P.R. China

Scope: Design and Development, Manufacture and Distribution of Disposable Syringes, Disposable Infusion Sets, Disposable Blood Transfusion Sets, Disposable Intravenous Needles, Disposable Hypodermic Needles, Extension Tubes for Single Use, Urine Bags for Single Use, Vaginal Speculums for Single Use, Nelaton Catheters, Suction Catheters, Feeding Tubes, Stomach Tubes, Rectal Tubes, Disposable I.D. Bracelets, Paediatric Urine Collectors, Wound Plasters, Medical Tapes, Medical Dressings, Disposable Insulin Syringes, Disposable Tourniquets, Auto-disable Syringes for Single Use, Disposable Irrigation Syringes, Disposable Syringes With Catheter Tip, Disposable Feeding Syringes, Disposable Dropper Tube Infusion Sets

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.: 326035522-200

Effective date: 2024-10-23

Expiry date: 2027-10-22

Issue date: 2024-10-23

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