

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 2183016-1

Certificate Holder: Changzhou Medical Appliances General Factory Co., Ltd.
Hengshanqiao Town, Wujin District,
Changzhou
213119 Jiangsu
P.R. China

Scope: Design and Development, Manufacture and Distribution of
Infusion Sets, Transfusion Sets, Syringes for Single Use,
Hypodermic Needles, Scalp Vein Sets, Oxygen Masks, Sterile
Nasal Oxygen Tubes, Re-usable Oral Syringes(with or without
Adaptors), Sterile Urine Bags, Sterile Latex Examination
Gloves, Sterile Vaginal Speculum, Sterile Urine Cups for
single use, Oral / Enteral Syringes for single use

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.: 326045179-200

Effective date: 2024-11-11

Expiry date: 2027-10-30

Issue date: 2024-11-11

Replaces certificate SX 2183016-1 issued 2022-12-07



Fuxiu Sheng

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

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