

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 2110300-1

Certificate Holder: Yangzhou Medline Industry Co., Ltd.
No. 108, Jinshan Road
Economic Development Zone
Yangzhou
225009 Jiangsu
P.R. China

Scope: Design and Development, Manufacture and Distribution of Nerve Block Needles (Anesthetic Needles), Disposable Non-absorbable Sutures with Needles, Disposable Insulin Syringes, Disposable Syringes, Three-way Stopcocks, Auto-disable Syringes, Disposable Infusion Sets, Hypodermic Needles, IV Catheters, Surgical Blades, Feeding Tubes, Stomach Tubes, Suction Catheters, Disposable Safety Auto-disable Syringes, Disposable Safety Hypodermic Needles, Scalp Vein Sets, Disposable Vacuum Blood Collection Needles, Disposable Safety Vacuum Blood Collection Needles, Disposable Safety Scalp Vein Sets, Disposable Urine Bags, Surgical Brushes, Retractable Safety Syringes (No Gap Type), Safety Vacuum Blood Collection Needles (Pen Type), Disposable Syringes with Safety Needles, Disposable Safety Insulin Syringes, Filter Needles for single use, Safety Lancets, Disposable Surgical Procedure Kits (Masks, Medical Gauze, applicator, Medical tape, Disposable syringe, Infusion sets), Pre-filled Flush Syringes, Disposable Feeding Syringes

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.: 326036845-200

Effective date: 2024-11-19

Expiry date: 2027-10-11

Issue date: 2024-11-19

Replaces certificate SX 2110300-1 issued 2024-06-05

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



Jin Hua Luo

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

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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Yangzhou Medline Industry Co., Ltd. No. 108, Jinshan Road Economic Development Zone Yangzhou 225009 Jiangsu P.R. China	License holder
/02	c/o Yangzhou Medline Industry Co., Ltd. No. 1, Huafa Road, Development Zone, Yangzhou, 225000 Jiangsu P.R. China	Design and Development, Manufacture and Distribution of Nerve Block Needles (Anesthetic Needles), Disposable Non-absorbable Sutures with Needles, Disposable Insulin Syringes, Disposable Syringes, Three-way Stopcocks, Auto-disable Syringes, Disposable Infusion Sets, Hypodermic Needles, IV Catheters, Surgical Blades, Feeding Tubes, Stomach Tubes, Suction Catheters, Disposable Safety Auto-disable Syringes, Disposable Safety Hypodermic Needles, Scalp Vein Sets, Disposable Vacuum Blood Collection Needles, Disposable Safety Vacuum Blood Collection Needles, Disposable Safety Scalp Vein Sets, Disposable Urine Bags, Surgical Brushes, Retractable Safety Syringes (No Gap Type), Safety Vacuum Blood Collection Needles (Pen Type), Disposable Syringes with Safety Needles, Disposable Safety Insulin Syringes, Filter Needles for single use, Safety Lancets, Disposable Surgical Procedure Kits(Masks, Medical Gauze, applicator, Medical tape, Disposable syringe, Infusion sets), Pre-filled Flush Syringes, Disposable Feeding Syringes
/03	c/o Yangzhou Medline Industry Co., Ltd. No. 99, South Yangzi Road, Yangzhou, 225000 Jiangsu P.R. China	Manufacture of Disposable Safety Hypodermic Needles

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