

中国国际贸易促进委员会 中国国际商会

China Council for the Promotion of International Trade
China Chamber of International Commerce

证明书

CERTIFICATE



号码 No. 241100B0/H50073

兹证明：所附文件的影印件与原件相符。

THIS IS TO CERTIFY THAT: the annexed photostated copy of
DOCUMENT is in conformity with the original.

China Council for the Promotion
of International Trade

签证员:

Authorized
Official: Gao Lichao

日期: 2024年11月25日
(Date: Nov. 25, 2024)

证 明 网 址 Website for verifying the certificate: <http://www.rzccpit.com/validate.html>



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rtificate

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

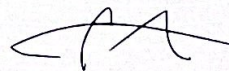
Scope: Design and Development, Manufacture and Distribution of Nerve Block Needles (Anesthetic Needles), Disposable Non-absorbable Sutures with Needles, Disposable Insulin Syringes, Disposable Syringes, Three-way Stopcocks, Auto-disable Syringes, Disposable Infusion Sets, Hypodermic Needles, IV Catheters, 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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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

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>





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附加证明书
APOSTILLE

(1961年10月5日海牙公约)
(Convention de La Haye du 5 octobre 1961)

1. 文书出具国: 中华人民共和国
Country: People's Republic of China

本公文书 This public document

2. 签署人
has been
signed by 高丽超
Gao Lichao

3. 签署人身份
acting in the
capacity of 签证员
Authorized Official

4. 印鉴名称
bears the
seal/stamp of 中国国际贸易促进委员会
China Council for the Promotion of International Trade

证明 Certified

5. 签发地
at 北京
Beijing

6. 签发日期
the 2024年11月27日
November 27, 2024

7. 签发人
by 赵军, 一等秘书/ Zhao Jun, First Secretary
外交部领事司
Department of Consular Affairs of the Ministry of Foreign Affairs



8. 附加证明书编号
No 认字第240000518418号

9. 签发机关印鉴:
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Signature:

赵军



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