

2024-10-09

To Whom It May Concern

This is to confirm that a Re-Certification Audit for ISO 13485 was carried out on behalf of TÜV Rheinland LGA Products GmbH Certification Body as follows:

Applicant: **Yangzhou Medline Industry Co., Ltd.**
Address: **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 Syringe**

Standards: **EN ISO 13485:2016+AC:2018+A11:2021**

Date: 2024-07-15~17

Report No.: 326036845-200

The result of on-site audit is positive, therefore the auditors will recommend that TÜV Rheinland LGA Products GmbH Certification Body Certificate for a Quality Management System should be issued.

Yours sincerely,
TÜV RHEINLAND (SHANGHAI) Co., Ltd.



Mr. Tony Chen
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