

**EC Certificate**  
**Directive 93/42/EEC Annex V**  
**Production Quality Assurance**  
**Medical Devices**

**Registration No.:** DD 60149237 0001

**Report No.:** 15064112 011

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

**Products:** Medical Devices  
  
(see attachment for scope and additional site included)  
  
Replaces Approval, Registration No.: DD 60134897 0001

**Expiry Date:** 2023-10-11

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

**Effective Date:** 2020-05-11

**Date:** 2020-05-11

Notified Body



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** DD 60149237 0001  
**Report No.:** 15064112 011

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

**Products:**

- 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
- Retractable Safety Syringes (No Gap Type)
- Safety Vacuum Blood Collection Needles (Pen Type)

**Date:** 2020-05-11

**Notified Body**

**Herbert Zhang**



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** DD 60149237 0001  
**Report No.:** 15064112 011

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

**Products:**

- Disposable Syringes with Safety Needles
- Disposable Safety Insulin Syringes
- Safety Lancets
- Disposable Surgical Procedure Kits (Masks, Medical Gauze, applicator, Medical tape, Disposable syringe, Infusion sets)

**Aspects of manufacture concerned with securing and maintaining sterile conditions:**

- Disposable Urine Bags
- Surgical Brushes
- Filter Needles for single use
- Pre-filled Flush Syringes
- Disposable Feeding Syringes

**Site included:**

Yangzhou Medline Industry Co., Ltd  
No. 1, Huafa Road, Development Zone, Yangzhou, Jiangsu  
225000, China

**Date:** 2020-05-11

**Notified Body**

**Herbert Zhong**

