

# EU Certificate

## Quality Management System REGULATION (EU) 2017/745 on Medical Devices Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.: HZ 2110300-1

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

EUDAMED Single  
Registration No.: CN-MF-000026644

Products: Products of class I, sterile:  
A020102-INFUSION AND IRRIGATION SYRINGES, SINGLE-  
USE  
- Disposable Syringes  
- Auto-disable Syringes  
- Safety Auto-disable Syringes  
- Disposable Safety Syringes  
- Retractable Safety Syringes  
A070103-INFUSION LINES ADAPTERS AND CONNECTORS  
- Three-way Stopcocks  
A019001-BLUNT NEEDLES  
- Dispensing Needles  
A020108-ENTERAL FEEDING SYRINGES  
- Disposable Feeding Syringes  
A060301-COLLECTION BAGS AND OTHER CONTAINERS

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.

If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 244489770-200

Effective date: 2024-08-01

Expiry date: 2029-07-31

Issue date: 2024-08-01



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

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

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

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**Annex IX Chapter I, Section 2 and 3 and Chapter III**

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FOR DRAINAGES AND FISTULAS, SINGLE USE  
- Disposable Urine Bags  
A030101-INFUSION CONTROLLERS  
- Infusion Sets  
A1101-SAMPLE COLLECTION NEUTRAL SWABS  
- Specimen Collection Swabs  
V9099-VARIOUS DEVICES NOT INCLUDED IN OTHER  
CLASSES - OTHER  
- Surgical Brushes  
T020604-MEDICAL USE FACE MASKS, TYPE II AND IIR  
- Disposable Medical Masks  
The scope of certification is limited to the aspects relating to  
establishing, securing and maintaining sterile conditions

Products of class IIa:  
A020106-INSULIN SYRINGES, SINGLE-USE  
- Disposable Insulin Syringes  
- Disposable Safety Insulin Syringes  
A020102-INFUSION AND IRRIGATION SYRINGES, SINGLE-  
USE  
- Disposable Syringes

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- Auto-disable Syringes
- Safety Auto-disable Syringes
- Disposable Safety Syringes
- Disposable Syringe with safety needles
- Retractable Safety Syringes
- A010102-BUTTERFLY NEEDLES
- Scalp Vein Sets
- Safety Scalp Vein Sets
- A010105-NEEDLES FOR COLLECTION UNDER VACUUM
- Vacuum Blood Collection Needles
- Safety Vacuum Blood Collection Needles
- A010101-HYPODERMIC NEEDLES
- Hypodermic Needles
- Safety Needles
- A030101-INFUSION CONTROLLERS
- Infusion Sets
- C010101-PERIPHERAL I.V. CATHETERS
- IV Catheters

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Authorized representative(s): Shanghai International Holding Corp. GmbH (Europe)  
Eiffestrasse 80, 20537 Hamburg, Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2024-08-01

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