TÜVRheinland®

EC Certificate

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

Registration No.: DD 60112152 0001

Report No.: 15064112 006

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

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60107494 0001

Expiry Date: 2018-10-11

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.

Notified Body

Effective Date: 2016-07-20

Date: 2016-07-20

X. Ren

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.

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60112152 0001
Report No.: 15064112 006

Manufacturer:
Yangzhou Medline Industry Co., Ltd.
No. 108, Jinshan Road
Economic Development Zone
Yangzhou
225009 Jiangsu
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
- Foley Catheters
- Nebulizers Masks
- ECG Electrode

Notified Body

Date: 2016-07-20

X. Ren

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60112152 0001
Report No.: 15064112 006

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

Products:

- Disposable Safety Scalp Vein Sets
- Retractable Safety Syringes (No Gap Type)
- Safety Vacuum Blood Collection Needles (Pen Type)
- Disposable Syringes with Safety Needles

Aspects of manufacture concerned with securing and maintaining sterile conditions:

- Disposable Urine Bags
- Surgical Brushes

Notified Body

TÜVRheinland LGA Products GmbH TÜVRheinland® Prüfzierungsstelle

X. Ren

Date: 2016-07-20

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