

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60145835 0001

Report No.: 15092033 007

Manufacturer: Gemtier Medical (Shanghai) Inc.
No. 18 Jianding Road
Fengjing Town, Jinshan District
201502 Shanghai
P.R. China

Products: Medical Devices

(see attachment for products and additional site included)

Replaces Approval, Registration No.: HD 60138645 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-01-19

Date: 2020-01-19



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.: HD 60145835 0001
Report No.: 15092033 007

Manufacturer: Gemtier Medical (Shanghai) Inc.
No. 18 Jianding Road
Fengjing Town, Jinshan District
201502 Shanghai
P.R. China

Products:

- Sterile Syringes for Single Use
- Sterile Needles for Single Use
- Sterile Syringes with Needles for Single Use
- Vein Nutrition-providing Infusion Bags for Single Use
- Safety Infusion Sets for Single Use
- Safety I.V Needles for Single Use
- Infusion Sets for Single Use
- Extension Tube with Flow Regulator for Single Use
- Sterile Infusion Pump for Single Use
- Safety Blood Collection Device for Single Use
- Sterile Connection Tube for Single Use
- Disposable Safety Retractable Blood Collection Needles
- Bag-type Infusion Sets with Needle for Single use
- Disposable Safety Blood Collection Device With Retractable Needles

Site included:

No. 6469 Tingfeng Road, Fengjing Town,
Jinshan District, Shanghai 201502, China

Date: 2020-01-19

