

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization  
**Gemtier Medical (Shanghai) Inc.**  
**No. 18 Jianding Road**  
**Fengjing Town, Jinshan District**  
**201502 Shanghai**  
**China**

has established and applies a quality management system for medical devices  
for the following scope:

**Design and Development, Manufacture and Distribution of  
Medical Devices**  
**(see attachment for products and additional site included)**

Proof has been furnished that the requirements specified in

## EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2019-08-02  
Certificate Registration No.: SX 60138648 0001  
An audit was performed. Report No.: 15092033 005  
This Certificate is valid until: 2022-04-10

Certification Body



Date 2019-08-02



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

Doc. 1/1, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** SX 60138648 0001  
**Report No.:** 15092033 005

**Organization:** Gemtier Medical (Shanghai) Inc.  
No. 18 Jianding Road  
Fengjing Town, Jinshan District  
201502 Shanghai  
China

**Scope:**

**Products:**

Sterile Syringes for Single Use, Sterile Needles for Single Use, Sterile Syringes with Needle 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 Tubes with Flow Regulator for Single Use, Sterile Infusion Pumps for Single Use, Safety Blood Collection Device for Single Use, Sterile Connection Tubes 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  
Manufacture of Sterile Syringes for Single Use, Sterile Needles for Single Use, Sterile Syringes with Needle for Single Use

**Certification Body**



**Date:** 2019-08-02

