

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

**Attachment to  
Certificate**

**Registration No.:** SX 60121554 0001  
**Report No.:** 15054142 008

**Organization:** Changzhou Shuangma  
Medical Devices Co., Ltd.  
San He Kou Development Zone,  
Zhenglu, Tianning  
Changzhou  
213115 Jiangsu  
China

**Scope:**

**Products:**

- Sterile Syringes for Single Use
- Sterile Infusion Sets for Single Use
- Sterile Hypodermic Needles for Single Use
- Gynecological Sets
- Cervical Samplers
- Urinary Collection Bags for Single Use
- Vaginal Speculums for Single Use

**Certification Body**



**Date:** 2017-08-14



# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Changzhou Shuangma  
Medical Devices Co., Ltd.  
San He Kou Development Zone,  
Zhenglu, Tianning  
Changzhou  
213115 Jiangsu  
China**

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

**Manufacture and Distribution of Medical Devices  
(see attachment for products 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: 2017-09-21  
Certificate Registration No.: SX 60121554 0001  
An audit was performed. Report No.: 15054142 008  
This Certificate is valid until: 2020-09-20

Certification Body



Date 2017-08-14



X. Ren

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>