

**APPROVAL**  
**EC Directive 93/42/EEC Annex II, Article 3**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60032473 0001

**Report No.:** 15037734 001

**Manufacturer:** Shandong Sinorgmed Co., Ltd.  
Middle Jinan Road  
Heze Development Zone

Shandong Province, Shandong 274000  
China

**Scope:** Design and Development, Manufacture of Medical Devices  
(see attachment for products included)

Replaces Approval, Registration No.: DD 60012916 0001

**Date of Expiry:** 24.08.2020

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Date 24.08.2015



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

Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and  
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. **0197** to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

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

**Attachment to**  
**Registration No.:** HD 60032473 0001  
**Report No.:** 15037734 001

**Manufacturer:** Shandong Sinorgmed Co., Ltd.  
Middle Jinan Road  
Heze Development Zone  
  
Shandong Province, Shandong 274000  
China

**Scope:** Products:  
  
- I.V. Cannulae  
- Suture Needles with Thread  
- Tri-way Stopcocks  
- Surgical Blades

**Date** 24.08.2015



**Certification Body**

X. Ren