

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

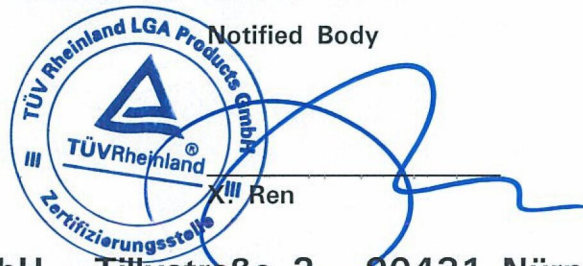
Shandong Province, Shandong 274000
China

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.



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



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

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