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.

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date 24.08.2015

X!!! Ren

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

Digitally signed by Potînga Stela
Date: 2020.02.04 12:11:06 EET
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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

Certification Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

X. Ren

Date 24.08.2015