APPROVAL

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

Registration No.: HD 60028451 0001

Report No.: 15034916 001

Manufacturer:
Hangzhou Jinlin
Medical Appliances Co., Ltd.
16th Ave., Hangzhou Economic &
Technological Development Zone

Hangzhou 310018
China

Scope: Design and Development, Manufacture of Tracheostomy Tubes

Replaces Approval, Registration No.: HD 60025405 0001

Date of Expiry: 04.02.2015

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

Date 05.02.2010

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