

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60119193 0001

Report No.: 15050608 008

Manufacturer: Nanchang Biotek Medical
Technology Co., Ltd.
No.738, Youkou Road, North Tianxiang Avenue
High-tech Development Zone
Nanchang
330072 Jiangxi
China

Products: Medical Devices
(see attachment for products included)
Replaces Approval, Registration No.: HD 60107770 0001

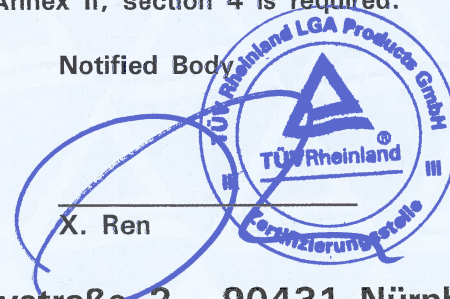
Expiry Date: 2022-06-28

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2017-07-06

Date: 2017-07-06

Notified Body



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev.0

**Attachment to
Certificate**

Registration No.: HD 60119193 0001
Report No.: 15050608 008

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Technology Co., Ltd.
No.738, Youkou Road, North Tianxiang Avenue
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Products:

- Foley Catheters
- Disposable Infusion Pumps
- Tracheal Tubes
- Reinforced Endotracheal Tubes
- HME Filters
- Laryngeal Mask Airways
- Double-lumen Laryngeal Mask Airways
- Tracheal Tube Kits
- Disposable Breathing Circuits
- I.V. Cannulas
- Anesthesia Masks

Aspects of manufacture concerned with securing and
maintaining sterile conditions:

- Laryngoscope Blades

Date: 2017-07-06

Notified Body

