TÜVRheinland®

EC Certificate

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

Registration No.: HD 60098613 0001

Report No.: 15077208 001

Manufacturer:
Hangzhou Jinlin
Medical Appliances Co., Ltd.
M14-3-4, Hangzhou Economic &
Technological Development Zone
Hangzhou
310018 Zhejiang
China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60076082 D001

Expiry Date: 2020-01-29

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: 2015-01-30

Date: 2015-01-30

TÜV Rheinland LGA Products GmbH Notified Body TÜVRheinland Zertifizierungsstelle

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.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60098613 0001
Report No.: 15077208 001

Manufacturer:
Hangzhou Jinlin
Medical Appliances Co., Ltd.
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310018 Zhejiang
China

Products:

- Tracheostomy Tubes
- Tracheal Tubes
- Stopcocks
- Suction Catheters
- Oxygen Masks
- Nasal Oxygen Cannulas
- Nebulizers
- Yankauer Suction Handles
- Extension Tubes
- Face Masks with Air Cushion
- CPR Masks
- Tracheostomy Masks
- Breathing Systems
- Disposable Anaesthesia Air Filters
- CVP Manometers

Aspects of manufacture concerned with securing and maintaining sterile conditions:

- Laryngoscope Blades

TÜV Rheinland LGA Products GmbH Notified Body TÜV Rheinland Zertifizierungsstelle

X. Ren

Date: 2015-01-30