

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

Registration No.: HD 60140292 0001

Report No.: 15077208 008

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

Products: Medical Devices

(see attachment for products and additional site included)

Replaces Approval, Registration No.: HD 60118053 0001

Expiry Date: 2024-05-26

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: 2020-01-20

Date: 2020-01-20



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. 1/2, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60140292 0001
Report No.: 15077208 008

Manufacturer: Hangzhou Jinlin
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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

Date: 2020-01-20

Notified Body



Fuxiu Sheng

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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Certificate**

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Report No.: 15077208 008

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

Site included:

No.18th, Guiling Road, Xuancheng Economic and Technological
Development Zone, Anhui Province, China

Date: 2020-01-20



Business Stream Products
Certification Department



TÜVRheinland®

LGA

Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Hangzhou Jinlin
Medical Appliances Co., Ltd.
M14-3-4, Hangzhou Economic &
Technological Development Zone
Hangzhou
310018 ZHEJIANG
P.R. CHINA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date January 20, 2020

Application for : Vollst. QMS, Anhang II MDD
Certificate No. : HD 60140292 Sheet 0001
Device : Only for QM-System audit
Test requirement : Richtlinie 93/42/EWG

Dear Madame or Sir,

Enclosed please find the new certificate No. HD 60140292 0001 replacing
the previous certificate.

With effective date of the new certificate, the previous certificate
(number see new certificate) becomes invalid.

Kind regards

Certification body

Fuxiu Sheng

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

Tel. +49 911 655-5225
Fax +49 911 655-5226
Mail service@de.tuv.com
Web www.tuv.com/safety

Board of Management

Dipl.-Ing.
Jörg Mähler, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Chairman of the
Supervisory Board

Dipl.-Ing.
Ralf Scheller

Nuremberg HRB 26013
VAT No.: DE 811835490