

**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**

**Attachment to  
Certificate**

**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:**

- 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**



**Fuxju Sheng**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**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

Site included:

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

**Date:** 2020-01-20



**Business Stream Products  
Certification Department**



**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](mailto: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](mailto:service@de.tuv.com)  
Web [www.tuv.com/safety](http://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