

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization  
**Jiangsu Rongye Technology  
Co., Ltd.**  
Touqiao Town  
Yangzhou City  
225109 Jiangsu  
P.R. China

has established and applies a quality management system for medical devices  
for the following scope:

**Manufacture and Distribution of Medical Devices**

**(see attachment for products included)**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2016**

are fulfilled. The quality management system is subject to yearly surveillance.


Effective Date: 2020-04-01  
Certificate Registration No.: SX 60148419 0001  
An audit was performed. Report No.: 15082365 010  
This Certificate is valid until: 2021-07-13

Certification Body



Date 2020-04-01



  
Fuxiu Sheng

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

**EC Certificate**  
**Directive 93/42/EEC Annex V**  
**Production Quality Assurance**  
**Medical Devices**

**Registration No.:** DD 60146205 0001

**Report No.:** 15082365 006

**Manufacturer:** Jiangsu Rongye Technology  
Co., Ltd.  
Touqiao Town  
Yangzhou City  
225109 Jiangsu  
P.R. China

**Products:** Medical Devices  
(see attachment for products included)

Replaces Approval, Registration No.: DD 60124435 0001

**Expiry Date:** 2024-05-26

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

**Effective Date:** 2020-02-24

**Date:** 2020-02-24



**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.:** DD 60146205 0001  
**Report No.:** 15082365 006

**Manufacturer:** Jiangsu Rongye Technology  
Co., Ltd.  
Touqiao Town  
Yangzhou City  
225109 Jiangsu  
P.R. China

**Products:**

Amniotic Membrane Perforators for single use, Gynecologic Samplers for single use, Blood Collection Needles for single use, Infusion Sets for single use, Syringes for single use, Nelaton Catheters for single use, Nasal Oxygen Tubes, Three-way Stopcocks (with Extension Tubes), Needle Free Connectors, Disposable Surgical Blades (with and without handle);

**Aspects of manufacture concerned with securing  
and maintaining sterile conditions:**

Otolaryngological Sets for single use, Liquid Drainage Device, Stomach Tubes for single use, Umbilical Cord Clamps for single use, Gynecological Sets for single use, Vaginal Speculums for single use, Tongue Depressors for single use, Ear Checkers for single use, Plastic Forceps, Medical Cups for single use, Urinary Drainage Bags for single use, Nasal Speculums, I.D. Bracelets for single use, Suction Catheters for single use, Medical Tapes, Wound Plasters, Medical Suction-connecting Tubes for single use, Medical Brushes, Sterile Surgical Packs, Disposable Dressings Kits

**Date:** 2020-02-24



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

**Attachment to  
Certificate**

**Registration No.:** SX 60148419 0001  
**Report No.:** 15082365 010

**Organization:** Jiangsu Rongye Technology  
Co., Ltd.  
Touqiao Town  
Yangzhou City  
225109 Jiangsu  
P.R. China

**Scope:**

Products:

Otolaryngological Sets for single use, Liquid Drainage Device, Amniotic Membrane Perforators for single use, Gynecologic Samplers for single use, Blood Collection Needles for single use, Infusion Sets for single use, Syringes for single use, Stomach Tubes for single use, Nelaton Catheters for single use, Nasal Oxygen Tubes, Three-way Stopcocks (with Extension tubes), Needle Free Connectors, Umbilical Cord Clamps for Single Use, Gynecological Sets for Single Use, Vaginal Speculums for Single Use, Tongue Depressors for Single Use, Ear Checkers for Single Use, Medical Suction-connecting Tubes for single use, Plastic Forceps, Medical Cups for single use, Urinary Drainage Bags for single use, Nasal Speculums, I.D. Bracelets for single use, Suction Catheters for single use;

**Certification Body**



**Date:** 2020-04-01



**Fuxiu Sheng**



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

**Attachment to  
Certificate**

**Registration No.:** SX 60148419 0001  
**Report No.:** 15082365 010

**Organization:** Jiangsu Rongye Technology  
Co., Ltd.  
Touqiao Town  
Yangzhou City  
225109 Jiangsu  
P.R. China

**Scope:** Products:

Medical Tapes, Wound Plasters, Skin Knives, Medical Brushes,  
Tourniquets, Disposable Surgical Blades (with and without  
handle), Sterile Surgical Packs, Disposable Dressing Kits,  
Face Masks, Oxygen Masks for single use, Venturi Masks for  
single use, Nebulizer Masks for single use, Oxygen Masks  
with Reservoir Bags for single use, Nebulizers with Mouth-  
pieces, Anesthesia Masks, Blood Collection Tubes,  
Viral Transport Kits, Viral Transport Tubes,  
Specimen Collection Swabs

**Certification Body**



**Date:** 2020-04-01



**Fuxiu Sheng**



**Business Stream Products**  
Certification Department



**TÜVRheinland®**  
**LGA**

Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Jiangsu Rongye Technology  
Co., Ltd.  
Touqiao Town  
Yangzhou City  
225109 JIANGSU  
P.R. CHINA

Contact

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Date April 02, 2020

**Application for : QMS**  
Certificate No. : SX 60148419 Sheet 0001  
Device : Only for QM-System audit  
Test requirement : EN ISO 13485:2016

Dear Madame or Sir,

Enclosed please find the  
new certificate No. SX 60148419 0001  
replacing the previous certificate.

Kind regards

Certification body

Fuxiu Sheng

Test sample: no, documentation available

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LGA Products GmbH

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90431 Nürnberg

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