

Certificate



Quality Management System
EN ISO 13485:2016

Registration No.: SX 2041633-1

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

Scope: Manufacture and Distribution of 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, 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, Nebulizrs with Mouth-pieces, Anesthesia Masks, Blood Collection Tubes, Viral Transport Kits, Viral Transport Tubes, Specimen Collection Swabs

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 244337407-200
Effective date: 2021-07-22
Expiry date: 2024-07-13
Issue date: 2021-07-22



Herbert Zhong
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



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



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

Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

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

Contact

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

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

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

