



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

Registration No.: HD 60147620 0001

Report No.: 15084181 009

Manufacturer: Jiangxi Yikang Medical Instrument
Group Co., Ltd.
No.188 Liduaihua Ave,
Jinxian County
331725 Nanchang, Jiangxi
P.R. China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60103576 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: 2020-04-08

Date: 2020-04-08

Notified Body

Jason Pan



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 60147620 0001
Report No.: 15084181 009

Manufacturer: Jiangxi Yikang Medical Instrument
Group Co., Ltd.
No.188 Liduaihua Ave,
Jinxian County
331725 Nanchang, Jiangxi
P.R. China

Products:

Sterile Urethral Catheters for Single Use, Intravenous Catheters for Single Use, Sterile Tracheal Tubes for Single Use, Sterile Tracheostomy Tubes for Single Use, Sterile Intubating Stylets for Single Use, Oxygen Masks, Nebulizers, Sterile Oropharyngeal Airways for Single Use, Sterile Nasopharyngeal Airways for Single Use, Laryngeal Mask Devices, Disposable Air Cushion Face Masks, Sterile Latex T-Drainage Tubes for Single Use, Sterile Pezzer Latex Catheters for Single Use, Sterile PVC Catheters for Single Use, Sterile Suction Catheters for Single Use, Sterile Stomach Tubes for Single Use, Sterile Feeding Tubes for Single Use, Sterile Blood Taking Sets for Single Use, Sterile Retraction Self Destruction Syringes for Single Use, Sterile Syringes for Single Use, Sterile Infusion Sets for Single Use, Sterile Hypodermic Needles for Single Use, Sterile Intravenous Needles for Single Use, Sterile Transfusion Sets for Single Use, Sterile Burette Type Infusion Sets for Single Use, Bag-type Infusion Sets for Single Use with Needles, Infusion Sets with Precision Filters for Single Use with Needles;

Date: 2020-04-08

Notified Body

Jason Pan
Jason Pan



The stamp is circular with a blue border. Inside the border, the text 'TÜV Rheinland LGA Products GmbH' is written at the top, 'TÜVRheinland' is in the center, and 'Zertifizierungsstelle' is at the bottom. In the center of the stamp is the TÜV Rheinland logo, a stylized blue triangle with a horizontal line through it.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60147620 0001
Report No.: 15084181 009

Manufacturer: Jiangxi Yikang Medical Instrument
Group Co., Ltd.
No.188 Liduaihua Ave,
Jinxian County
331725 Nanchang, Jiangxi
P.R. China

For the following medical devices the scope covers only
the aspects of manufacture concerned with securing and
maintaining sterile conditions:

Sterile Vaginal Dilators for Single Use, Face
Masks for Single Use

Date: 2020-04-08

Notified Body

Jason Pan



Certificate



**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 2030345-1

Organization: Jiangxi Yikang Medical
Instrument Group Co., Ltd.
No.188, Liduaihua Ave, Jinxian County,
Nanchang, 331725
Jiangxi
P.R. China

Scope: Design and Development, Manufacture and Distribution of Intravenous Catheters for Single Use, Sterile Syringes for Single Use, Sterile Infusion Sets for Single Use, Sterile Hypodermic Needles for Single Use, Sterile Intravenous Needles for Single Use, Sterile Transfusion Sets for Single Use, Sterile Burette Type Infusion Sets for Single Use, Sterile Blood Taking Sets for Single Use, Sterile Vaginal Dilators for Single Use, Bag-type Infusion Sets for Single Use with Needles, Face Masks for Single Use, Sterile Urethral Catheters for Single Use, Infusion Sets with Precision Filters for Single Use with Needles, Sterile Tracheal Tubes for Single Use, Sterile Tracheostomy Tubes for Single Use, Sterile Intubating Stylets for Single Use, Oxygen Masks, Nebulizers, Sterile Oropharyngeal Airways for Single Use, Sterile Nasopharyngeal Airways for Single Use, Laryngeal Mask Devices, Disposable Air Cushion Face Masks, Sterile Latex T-Drainage Tubes for Single Use, Sterile Pezzer Latex Catheters for Single Use, Sterile PVC Catheters for Single Use, Sterile Suction Catheters for Single Use, Sterile Stomach Tubes for Single Use, Sterile Feeding Tubes for Single Use, Sterile Retraction Self Destruction Syringes for Single Use

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.: 244331387-200
Effective date: 2021-09-22
Expiry date: 2024-08-04
Issue date: 2021-09-22



Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

