

## Certificate

The Certification Body of TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

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

Design and Development, 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:

2018-09-10

Certificate Registration No.:

SX 60131969 0001

An audit was performed. Report No.: 15084181 005

This Certificate is valid until:

2021-08-04

Certification Body



Date 2018-09-10



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



TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg Doc. 1/2, Rev. 0

Attachment to Certificate

Registration No.:

SX 60131969 0001

Report No .:

15084181 005

Organization:

Jiangxi Yikang Medical Instrument Group Co., Ltd. No.188 Liduaihua Ave,

Jinxian County

331725 Nanchang, Jiangxi

China

Scope:

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

Certification Body



Date: 2018-09-10





Doc. 2/2, Rev. 0

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

Attachment to Certificate

Registration No.:

SX 60131969 0001

Report No .:

15084181 005

Organization:

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

Scope:

Products:

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

Certification Body



Date: 2018-09-10

