

## Certificate

The Certification Body of TUV Rheinland LGA Products GmbH

hereby certifies that the organization

Shandong Kanglilai Medical Apparatus Co., Ltd. No. 8 Xinchang Road, Changyi City Shandong Province, 261300 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:** 

2019-07-01

Certificate Registration No.:

SX 60139114 0001

An audit was performed. Report No.: 16803032 007

This Certificate is valid until:

2022-04-16

Certification Body



Date 2019-07-01



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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Doc. 1/1, Rev. 0

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

Attachment to Certificate

Registration No.:

DD 60139113 0001

Report No.:

16803032 007

Manufacturer:

Shandong Kanglilai Medical

Apparatus Co., Ltd.

No. 8 Xinchang Road, Changyi City

Shandong Province, 261300

China

## Products:

- Disposable Syringes with Needles
- Disposable Infusion Sets
- Disposable Intravenous Needles
- Disposable Hypodermic Needles
- Disposable Blood Transfusion Sets
- Disposable Nasogastric Tubes

Aspects of manufacture concerned with securing and maintaining sterile conditions:

- Sterile Urine Bags

Date: 2019-07-01

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