TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Zhejiang Kangkang
Medical-Devices Co., Ltd.
Longwang Industrial District,
Chumen Town, Yuhuan County
Zhejiang Province 317605
China

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

Manufacture and Distribution of Disposable Medical Devices

Proof has been furnished that the requirements specified in

EN ISO 13485:2012
EN ISO 13485:2012/AC:2012

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

Certificate Registration No.: SX 60086566 0001

An audit was performed. Report No.: 15060987 001

This Certificate is valid until: 21.07.2018

Certification Body

Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-995.00.01-46

Date 22.07.2013

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle
Ren

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 60086565 0001

Report No.: 15060987 001

Manufacturer:
Zhejiang Kangkang
Medical-Devices Co., Ltd.
Longwang Industrial District,
Chumen Town, Yuhuan County
Zhejiang Province 317605
China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60021943 0001

Expiry Date: 2018-07-21

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: 2013-07-22

Date: 2013-07-22

Notified Body

X. Ren

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.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60086565 0001
Report No.: 15060987 001

Manufacturer:
Zhejiang Kangkang
Medical-Devices Co., Ltd.
Longwang Industrial District,
Chumen Town, Yuhuan County
Zhejiang Province 317605
China

Products:

- Sterile Hypodermic Syringes for Single Use
- Infusion Sets for Single Use
- Intravenous Needles for Single Use
- Sterile Auto-disable Syringes for Single Use
- Sterile Retractable Safety Syringes for Single Use
- Sterile Hypodermic Needles for single use

Date: 2013-07-22

Notified Body

X. Ren