EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60132680 0001

Report No.: 15060987 007

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

Digitally signed by Dicusar Vladimir
Date: 2021.09.27 09:34:16 EEST
Reason: MoldSign Signature
Location: Moldova

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60086565 0001

Expiry Date: 2023-07-21

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: 2019-01-07

Date: 2019-01-07

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Herbert Zhong

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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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60132680 0001
Report No.: 15060987 007

Manufacturer:
Zhejiang Kangkang
Medical-Devices Co., Ltd.
Longwang Industrial District
Chumen Town
Yuhuan
317605 Zhejiang
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: 2019-01-07

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Herbert Zhong