EC Certificate

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

Registration No.: DD 60140171 0001

Report No.: 15062350 009

Manufacturer:
Anhui JN Medical Device Co., Ltd.
Caicun Town, Jing County
Xuancheng City
242525 Anhui
China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60135530 0001

Expiry Date: 2023-10-18

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: 2019-06-19

Date: 2019-06-19

Notified Body

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

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 60140171 0001
Report No.: 15062350 009

Manufacturer:
Anhui JN Medical Device Co., Ltd.
Caicun Town, Jing County
Xuancheng City
242525 Anhui
China

Products:

Infusion Sets for Single Use, Scalp Vein Sets for Single Use, Transfusion Sets for Single Use, Sterile Hypodermic Syringes for Single Use, Sterile Hypodermic Needles for Single Use, Infusion Sets with Precision Filters for Single Use, Disposable Insulin Syringes;

Aspects of manufacture concerned with securing and maintaining sterile conditions:

Irrigation Syringes, Disposable Transfer Sets

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Fuxiu Sheng

Date: 2019-06-19