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Certificate

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

TÜVRheinland®

Registration No.: DD 60144902 0001

Report No.: 15096089 007

Manufacturer:
Changzhou Holinx Industries
Co., Ltd.
No. 1 Dongtang Road
Zhenglu Town, Tianning District
Changzhou
213115 Jiangsu
China

Products:
Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60127504 0001

Expiry Date: 2024-05-27

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: 2019-12-02

Date: 2019-12-02

Notified Body
TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle
Fuxiu Sheng

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 60144902 0001
Report No.: 15096089 007

Manufacturer:
Changzhou Holinx Industries Co., Ltd.
No. 1 Dongtang Road
Zhenglu Town, Tianning District
Changzhou
213115 Jiangsu
China

Products:

- Syringes for Single Use
- Infusion Sets for Single Use
- Hypodermic Needles for Single Use
- Intravenous Needles for Single Use

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Vaginal Speculums for Single Use
- Urine Bags for Single Use

Notified Body

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

Fuxiu Sheng

Date: 2019-12-02

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