EC Certificate

TÜVRheinland®

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

Registration No.:	DD 2068393-1
Manufacturer:	Changzhou Hekang Medical Instruments Co., Ltd. Room 1106, 301 Tongjiang Central Road, Xinbei District, Changzhou, 213022 Jiangsu P.R. China
Products:	Disposable Syringes, Disposable Infusion Sets, Disposable Hypodermic Needles, Disposable Insulin Syringes; Aspects of manufacture concerned with securing and maintaining sterile conditions: Urinary Collection Bags

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.

Report No.:	15095651 008
Effective date:	2021-03-31
Expiry date:	2024-05-26
Issue date:	2021-03-31

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Herbert Zhong
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Declaration of Conformity

Manufacturer:

Changzhou Hekang Medical Instruments Co., Ltd.
Room 1106, 301 Tongjiang Central Road, Xinbei District, Changzhou, 213022 Jiangsu, P.R. China

whose single Authorized Representative:

Name：Caretechion GmbH
Add: Niederrheinstr. 71, 40474 Dusseldorf, Germany
Tel：+49 211 3003 6618
Fax：+49 211 3003 6619
Contact Person Mr.Jian Wang
Dimdi Code DE/0000048026
E-mail：info@caretechion.de

We, the manufacturer, herewith declare that the products covering following products:

Sterile Urinary Collection Bags for single use, Is, rule 1

ART No. 74.5283.005 74.5284.005 74.5228.005
74.5281.005 74.5282.005 74.5286.005

*(*including system components and accessories*)*

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class Is according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been designed and manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body.

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
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following the procedure relating to the EC Declaration of Conformity set out in Annex V of Directive 93/42/EEC.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company:Changzhou Hekang Medical Instruments Co., Ltd.
Address: *Room 1106, 301 Tongjiang Central Road, Xinbei District, Changzhou, 213022 Jiangsu, P.R. China*

CHANGZHOU, JULY 17, 2021
Place , date

常州和康医疗器材有限公司
CHANGZHOU HEKANG MEDICAL INSTRUMENTS CO.,LTD

Legally binding signature, Function