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

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

EU DECLARATION OF CONFORMITY

Name and address of the manufacturer: /	Changzhou Hekang Medical Instruments Co., Ltd. Room 1106, Xinhui Mansion, 301 Tongjiang Road, Changzhou, Jiangsu, 213022 China
EC Authorized Representative:/	Oxford Medico Europe Limited 6-9 Trinity Street, Dublin 2, D02 EY47 Ireland

We declare under our sole responsibility that

Name of the medical device: /	Urinary Collection Bags (Non-sterile) Model : 2000ml ; 1500ml
Product code:/	74.5281.101 ; 74.5283.101 ; 74.5218.101 ; 74.5282.101 ; 74.5284.101 ; 74.5228.101
Intended purpose : /	The Urinary Collection Bag is intended to be connected to an indwelling catheter to collect urine.
of class: /	Class I, Rule1

according to annex VIII of Regulation (EU) 2017/745. It bears the mark CE /

Conformity assessment: /	Declare the conformity of the abovementioned products by issuing this EU Declaration of Conformity after drawing up the technical documentation set out in Annexes II and III of Regulation (EU) 2017/745 / according to Article 52(7) of Regulation (EU) 2017/745 / The product concerned has been designed and manufactured under a quality management system according to Regulation (EU) 2017/745 /

The product meets the provisions of the Regulation (EU) 2017/745 and its transpositions in national laws which apply to it. /

CHANGZHOU, DEC.22, 2020
Place, date /

CHANGZHOU HEKANG MEDICAL INSTRUMENTS CO., LTD.

Name and function /