

Certificate



**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 2090817-1

Organization: Changzhou Kenno Medical Instruments
Co., Ltd.
No.2188, Longcheng Road,
Xinzha Street, Zhonglou District,
Changzhou
213012 Jiangsu
P.R. China

Scope: Manufacture and Distribution of Disposable IV Catheters, Safety Needles,
Needle Free Connectors, Three-Way Stopcocks, Heparin Caps, Combi
Stoppers, Suction Catheters, Feeding Tubes, Connecting Tubes, Urinary
Collection Bags, Nelaton Catheters, Hand Scrub Brushes, Vomit Bags,
Bowls, Deep Trays, Spigots(Plug), Disposable Medical Face Masks

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 244358097-200
Effective date: 2021-12-24
Expiry date: 2024-10-22
Issue date: 2021-12-24



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

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

Registration No.: DD 60136083 0001

Report No.: 15063282 007

Manufacturer: Changzhou Kenno Medical
Instruments Co., Ltd.
No. 2188, Longcheng Road
Xinzha Street, Zhonglou District
Changzhou
213012 Jiangsu
China

Products: Medical Devices
(see attachment for products included)

Replaces Approval, Registration No.: DD 60103797 0001

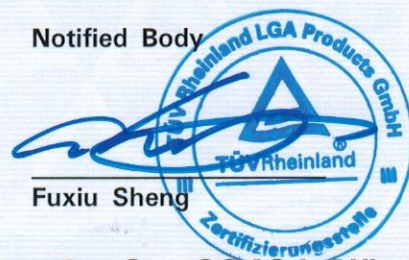
Expiry Date: 2023-10-22

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: 2019-07-11

Date: 2019-07-11

Notified Body



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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

**Attachment to
Certificate**

Registration No.: DD 60136083 0001
Report No.: 15063282 007

Manufacturer: Changzhou Kenno Medical
Instruments Co., Ltd.
No. 2188, Longcheng Road
Xinzha Street, Zhonglou District
Changzhou
213012 Jiangsu
China

Products:

- Safety Needles
- Disposable IV Catheters
- Needle Free Connectors
- Three-Way Stopcocks
- Heparin Caps
- Suction Catheters
- Feeding Tubes
- Combi Stoppers
- Connecting Tubes

Aspects of manufacture concerned with securing and
maintaining sterile conditions:

- Urinary Collection Bags
- Nelaton Catheters
- Hand Scrub Brushes
- Vomit Bags
- Bowls
- Deep Trays
- Spigots (Plug)

Date: 2019-07-11

Notified Body



Fuxiu Sheng