

# EC Declaration of Conformity

## Manufacturer:

Shandong kanglilai Medical Apparatus Co., Ltd.  
No.8, Xinchang Road, Changyi City, Shandong  
Province 261300, China  
Phone: 0086-536-7229178  
E-mail: sdkanglilai@163.com

## European Representative:

Shanghai International Holding Corp.GmbH  
(Europe).  
Eiffestrasse 80,20537 Hamburg, Germany  
Tel: +49-40-2513175 Fax: +49-40-255726  
Email: shholding@hotmail.com

We, the manufacturer, herewith declare that the products

Disposable Infusion Sets  
Model( IV-6-1Y ,IV-6-3, IV-6-5, IV-6-5Y, IV-6-6 )

UMDNS-Code: **17825**

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

The medical device has been assigned to class IIa 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**

Certificate No.:DD 2111681-1

Issue date: 2020-11-15

Expiry date:2024-04-16

following the procedure relating to the EC Declaration of Conformity set out in Annex V of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark

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

Company: Shandong kanglilai Medical Apparatus Co., Ltd

Address: No.8, Xinchang Road, Changyi City, Shandong Province 261300, China

Changyi 2021.12.10

Place, date

