

EC Declaration of Conformity

Manufacturer:

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Eiffestrasse 80,20537 Hamburg, Germany
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We, the manufacturer, herewith declare that the products

Disposable Blood Transfusion Sets

Model(BT-3、BT-5、BT-3S)

UMDNS-Code: 10421

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


Legally binding signature, Function