EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60147247 0001

Report No.: 15056334 012

Manufacturer:

Jiaxing Tianhe
Pharmaceutical Co., Ltd.
Zhongfa Foreign Trade Industrial
Zone, Fengqiao Town, Nanhu District
314008 Jiaxing City, Zhejiang Province
P.R. China

Products:

Disposable Plastic Blood Bags, Disposable Leukocyte Reduction Filters, Disposable Plastic Blood Bags with Leukocyte-reduced Filter, Pre-filled Flush Syringes

Replaces Approval, Registration No.: HD 60125133 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2021-04-09

Date: 2021-04-09

Notified Body

Fuxiu Sheng

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.

Digitally signed by Bolea Petru
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