

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

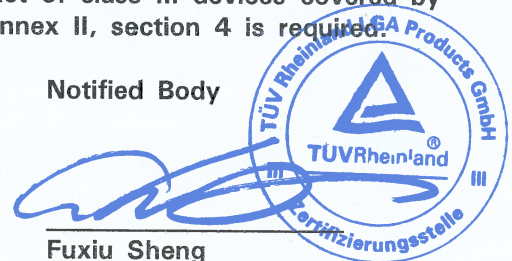
Expiry Date: 2024-05-26

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



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.