



**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.