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EC Certificate

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

Registration No.: HD 60125133 0001

Report No.: 15056334 009

Manufacturer:
Jiaxing Tianhe
Pharmaceutical Co., Ltd.
Zhongfa Foreign Trade Industrial
Zone, Fengqiao Town, Nanhu District
314008 Jiaxing City, Zhejiang Province
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 60119703 0001

Expiry Date: 2022-12-11

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: 2017-12-13

Date: 2017-12-13

Notified Body
TÜV Rheinland LGA Products GmbH
TÜVRheinland
III III
Zertifizierungsstelle
X. Ren

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.