TÜVRheinland®

EC Certificate

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

Registration No.: HD 60135869 0001

Report No.: 15096340 002

Manufacturer:

Zhengyuan Technology Co., Ltd.
No. 9 East Fengsi Road, Fengjing
Industrial Park, Huyi District
Xi'an
710300 Shaanxi
P.R. China

Products:

- Plasma Separators for Single Use
- Centrifugal Blood Processing Bowls for Single Use
- Apheresis Tubing Sets for Single Use
- Apheresis Needle Assemblies for Single Use
- Plasma Component Bags for Single Use
- Plasma Collection Bottles for Single Use

Expiry Date: 2024-01-24

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: 2020-01-14

Date: 2020-01-14

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Herbert Zhong

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.