

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

has established and applies a quality management system for medical devices
for the following scope:

Design and Development, Manufacture and Distribution of
Medical Devices
(see attachment for products included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-01-14
Certificate Registration No.: SX 60135871 0001
An audit was performed. Report No.: 15096340 002
This Certificate is valid until: 2022-01-24

Certification Body



Date 2020-01-14



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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60135871 0001
Report No.: 15096340 002

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

Scope:

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

Certification Body



Date: 2020-01-14

