

## Certificate

The Certification Body of TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Zhengyuan Technology Co., Ltd. A-7 Floor, Huajing Business Square, No.20, South Fenghui Road 710075 Xi'an, Shaanxi

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 and additional site included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2012 EN ISO 13485:2012/AC:2012

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

Effective Date:

2017-08-07

Certificate Registration No.:

SX 60119447 0001

An audit was performed. Report No.: 15068314 005

This Certificate is valid until:

2019-02-28

Certification Body



Date 2017-08-07



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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Doc. 1/1, Rev.0

# TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Attachment to Certificate

Registration No.:

SX 60119447 0001

Report No.:

15068314 005

Organization:

Zhengyuan Technology Co., Ltd. A-7 Floor, Huajing Business Square,

No.20, South Fenghui Road 710075 Xi'an, Shaanxi

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 Machines
- Plasma Collection Bottles for Single Use

Site included:

Eastern part of the 4th Feng Road, Fengjing Industry Park, Xi'an Economic & Technological Development Zone, Xi'an, Shaanxi 710300, China

Design and Development, Manufacture and Distribution of the a.m. products

### **Certification Body**



Date: 2017-08-07

