

**EC Certificate**  
**Directive 93/42/EEC Annex V**  
**Production Quality Assurance**  
**Medical Devices**

Registration No.: DD 60121551 0001

Report No.: 15054142 008

**Manufacturer:** Changzhou Shuangma  
Medical Devices Co., Ltd.  
San He Kou Development Zone,  
Zhenglu, Tianning  
Changzhou  
213115 Jiangsu  
China

**Products:** Medical Devices

(see attachment for products included) ®

Replaces approval, registration no.: DD 60106171 0001

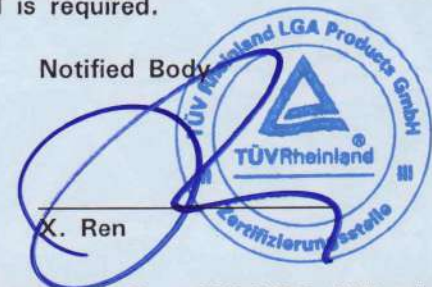
**Expiry Date:** 2022-09-20

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

**Effective Date:** 2017-09-21

**Date:** 2017-08-14

Notified Body



**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.