# 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

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.

Digitally signed by Guţan Ghenadie
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