

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: DD 60078608 0001
Report No.: 15054142 001

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

Products:

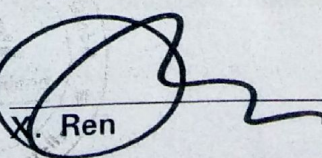
- Sterile Syringes for Single Use
- Sterile Infusion Sets for Single Use
- Sterile Hypodermic Needles for Single Use
- Sterile Intravenous Needles for Single Use

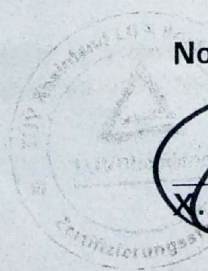
For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Urinary Collection Bags for Single Use
- Vaginal Dilators for Single Use
- Gynecological Sets
- Cervical Brushes
- Cervical Spatula

Date: 2012-09-21

Notified Body


X. Ren



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

Registration No.: DD 60078608 0001

Report No.: 15054142 001

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

Products: Medical Devices

(see attachment for products included)

Replaces approval, registration no.: DD 60018941 0001

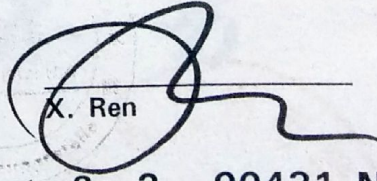
Expiry Date: 2017-09-20

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: 2012-09-21

Date: 2012-09-21

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.

NOTARIAL CERTIFICATE

公 证 书

(2015)常常证经外字第66号

申请人：常州市双马医疗器材有限公司，住所：武进区郑陆镇三河口开发区。

法定代表人：冯国林，男，一九五八年四月十八日出生，公民身份号码：32042119580418605X。

委托代理人：冯斌，男，一九八八年七月二十九日出生，公民身份号码：320402198807293410。

公证事项：复印件与原本相符

兹证明前面的复印件内容与常州市双马医疗器材有限公司的委托代理人冯斌出示给本公证员的英文本的原本相符。

中华人民共和国江苏省常州市常州公证处

公证员

徐芳

二〇一五年二月九日



1167041358

NOTARIAL CERTIFICATE
(Translation)

(2015) CCZ JW Zi, No.66

Applicant: Changzhou Shuangma Medical Devices Co., Ltd.; Domicile: Sanhekou Development Zone, Zhenglu Town, Wujin District.

Legal representative: Feng Guolin, male, born on April 18, 1958, ID No. 32042119580418605X.

Agent: Feng Bin, male, born on July 29, 1988, ID No. 320402198807293410.

Issue under notarization: Photocopy in conformity with the original copy

This is to certify that the photocopy attached hereto is in conformity with the original English copy presented to the notary by Feng Bin, the agent of Changzhou Shuangma Medical Devices Co., Ltd.

Notary: Xu Fang (Signature)
Changzhou Notary Public Office (Seal)
Changzhou City, Jiangsu Province
The People's Republic of China
February 9, 2015

I 167041357