

## APPROVAL

EC Directive 93/42/EEC Annex V, Article 3  
Quality Assurance System Production

Registration No.: DD 60018941 0001

Report No.: 15023228 001

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

Jiangsu 213115  
China


**Scope:** Manufacturing of medical devices  
Products: see attachment  
Replaces approval, registration no.: DD 60003040 0001

**Date of Expiry:** 02.10.2012

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex V, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex V, Article 4 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Cologne, 23.10.2007

Notified Body

  
Dipl.-Ing. D. Meier



**TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln**  
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and  
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. **0197** to the EC Commission.



**TÜV Rheinland**  
**Product Safety GmbH**  
Am Grauen Stein, D-51105 Köln

**Attachment to**  
**Registration No.:** DD 60018941 0001  
**Report No.:** 15023228 001

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

**Scope:** 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

Cologne, 23.10.2007



Dipl.-Ing. D. Meier