



Product Service

# EC Certificate

## Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

**No. G2S 17 11 76830 011**

**Manufacturer:** **Changzhou Chuangjia Medical Appliance Co., Ltd.**  
 Sanhekou Development Zone, Zhenglu Town  
 213115 Changzhou  
 PEOPLE'S REPUBLIC OF CHINA



**EC-Representative:** **Lotus Global Co., Ltd.**  
 1 Four Seasons Terrace  
 West Drayton, Middlesex  
 London  
 UB7 9GG  
 UNITED KINGDOM

**Product Category(ies):** **Sterile Vaginal Speculum, Sterile Vaginal Irrigator, Sterile Medical Mouthpiece, Sterile Urine Drainage Bag, Sterile Medical Sampler, Sterile Gynecological Examination Set, Disposable Irrigation Syringe (Feeding Syringe)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

**Report No.:** SH1767407

**Valid from:** 2018-03-12  
**Valid until:** 2022-01-09

**Date,** 2018-03-12

*S. Preiß*  
 Stefan Preiß



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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