



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 16 01 72517 009

**Manufacturer:** **Changzhou Shunfeng Plastic Co., Ltd.**

Shunbei Country  
 Zhenglu Town  
 Tianning District  
 213116 Changzhou City, Jiangsu Province  
 PEOPLE'S REPUBLIC OF CHINA



**EC-Representative:** **Shanghai International Holding Corp. GmbH (Europe)**

Eiffestraße 80  
 20537 Hamburg  
 GERMANY

**Product Category(ies):** **Sterile Vaginal Speculum for Single Use, Disposable Colostomy Bag for Single Use, Sterile Vaginal Irrigation Set for Single Use, Urine Bag for Single Use, Gynecological Set for Single Use, Cervical Brushes**

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.:** SH1658207

**Valid from:** 2016-02-16

**Valid until:** 2020-03-18

**Date,** 2016-02-16

Stefan Preiß



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

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