Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD 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 072517 0009 Rev. 01

Manufacturer

Changzhou Shunfeng Plastic Co., Ltd.
Shunbei Country
Zhenglu Town
Tianning District
213116 Changzhou City, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

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.: SH19582EXT01

Valid from: 2019-08-13
Valid until: 2024-05-26

Date, 2019-08-13

Stefan Preiß
Head of Certification/Notified Body

Digitally signed by Potînga Stela
Date: 2021.11.29 13:39:39 EET
Reason: MoldSign Signature
Location: Moldova

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV SÜD ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17