ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 03 39452 027

Manufacturer:

Jiangsu Kangjin Medical Instrument Co., Ltd.
Zhenglu Town
213111 Changzhou
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):

Vaginal Speculum and Urine Bag for Single Use,
Manual Vacuum Aspirator Instrument for Gynecological Use,
Flexible Cannula for Gynecological Use,
Gynecological Set for Single Use,
Sampling Device for Single Use,
Cervical Probe and Dilator for Gynecological Use,
Cytology Brushes for Single Use,
Mouth Guards for Single Use

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.: SH16085EXT01

Valid from: 2016-03-18
Valid until: 2021-03-13

Date, 2016-03-18

Stefan Preiß

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

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Facility(ies):

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Zhenglu Town, 213111 Changzhou, PEOPLE'S REPUBLIC OF CHINA

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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