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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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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 039452 0032 Rev. 02

Manufacturer

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

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, Biopsy Valve for Single Use, The Connection / Extension Tube for Single Use, Irrigation Sets for Single Use, Syringes (Without Needles), Parenteral Nutrient Infusion Sets for Single Use (Without Needles), Enteral Feeding Set for Single Use (Gravity Feed)

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.: SH19085EXT01

Valid from: 2019-12-02
Valid until: 2024-05-26

Date, 2019-12-02

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Moraru Grigore
Date: 2023.11.10 10:45:10 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

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

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