ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ 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 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

Stefan Preiß

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

Digitally signed by Chitic Ecaterina
Date: 2020.12.11 18:04:23 EET
Reason: MoldSign Signature
Location: Moldova

Digitally signed by Chitic Vlad
Date: 2020.08.12 22:28:29 EEST
Reason: MoldSign Signature
Location: Moldova

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Facility(ies):

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213115 Changzhou, PEOPLE'S REPUBLIC OF CHINA

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

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