



Product Service

Certificate

No. Q5 039452 0034 Rev. 00

Holder of Certificate: **Jiangsu Kangjin Medical Instrument Co., Ltd.**

Zhenglu Town
213111 Changzhou
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Design and Development, Production and Distribution of Vaginal Speculum, Urine Bag, Biopsy Forceps, Manual Vacuum Aspirator Instrument for Gynecological Use, Flexible Cannula for Gynecological Use, Gynecological Set for Single Use, Sampling Device for Single Use, Brush for Endoscope Cleaning, Cervical Probe and Dilator for Gynecological Use, Cytology Brushes for Single Use, Mouth Guards for Single Use, Enteral Feeding Set for Single Use, Infusion Sets, Transfusion Sets, Syringes, Scalp Vein Sets, Injection Needles, Light-resistant Infusion Sets for Single Use, The Connection/Extension Tube for Single Use, Infusion Sets with Precision Filters for Single Use, Parenteral Nutrient Infusion Sets for Single Use, Grasping Forceps for Single Use, Electrosurgical Snares for Single Use, Hot Biopsy Forceps for Single Use, Irrigation Sets for Single Use, Light-resistant Infusion Sets with Precision Filters for Single Use, Light-resistant Scalp Vein Sets for Single Use, Endoscopic Injection Needle for Single Use, Washing Pipe for Single Use, Biopsy Valve for Single Use, Endoscopic Hemoclip for Single Use

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1808519
Valid from: 2019-05-27
Valid until: 2022-01-31

Date, 2019-05-27

Stefan Preiß
Head of Certification/Notified Body



Product Service

Certificate

No. Q5 039452 0034 Rev. 00

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): Jiangsu Kangjin Medical Instrument Co., Ltd.
Zhenglu Town, 213111 Changzhou, PEOPLE'S
REPUBLIC OF CHINA

EC-Declaration of Conformity



According to appendix VII Directive 93/42/EEC

We,

JIANGSU KANGJIN MEDICAL INSTRUMENT CO., LTD,**Located at ZHENGLU TWON 213111, CHANGZHOU, JIANGSU, CHINA**

declare that the Medical Devices Class I according to appendix IX Directive 93/42/EEC with the description **DISPOSABLE CLEANING BRUSH FOR ENDOSCOPY** which made of PA Nylon and POM conform in all aspects to those mentioned on appendix I Directive 93/42/EEC.

JIANGSU KANGJIN MEDICAL INSTRUMENT CO., LTD

JIANGSU KANGJIN MEDICAL INSTRUMENT CO., LTD.

 President

CHANGZHOU, JIANGSU, CHINA

2020-01-16

JIANGSU KANGJIN MEDICAL INSTRUMENT CO., LTD.

Add: Zhenglu Town, Changzhou, Jiangsu Province, China 213111

Tel: +86-519-88736801 / 85065058 Fax: +86-519-88731331

www.kangjin.cn