康进 KANGJIN

Forward the health

Declaration of Conformity

Manufacturer: Jiangsu Kangjin Medical Instrument Co., Ltd Address: Zhenglu Town, Changzhou, Jiangsu Province, PRC	European Representative: Shanghai International Holding Crop. GmbH Address： Eiffestrasse 80, D-20537 Hamburg, Germany

Product Name	Model Number	UMDNS / GMDN CODE	Product Classification (MDD, Annex IX)	Conformity Assessment Route	(EC)Certificate(s) Number	Start of CE Marking	Certificate Expire date
Biopsy forceps for single use	FB-AST, FB-ATG, FB-AES, FB-AEG, FB-BTS, FB-BTG, FB-BES, FB-BEG, FB-CTS, FB-CTG, FB-CES, FB-CEG, FB-DTS, FB-DTG, FB-DES, FB-DEG	16268	IIa, Rule 6	Annex II, excluding 4	G1 039452 0033 Rev.01	2006-04-15	2024-05-26
Electrosurgical snare for single use	SD-T, SD-L, SD-Y	61455	IIb, Rule 9	Annex II, excluding 4	G1 039452 0033 Rev.01	2016-03-17	2024-05-26
Grasping forceps for single use	FG-A, FG-B, FG-C, FG-D, FG-E	15628	IIa, Rule 5	Annex II, excluding 4	G1 039452 0033 Rev.01	2016-03-17	2024-05-26
Endoscopic Injection Needles for single use	IN-A, IN-B	17569	IIa, Rule 6	Annex II, excluding 4	G1 039452 0033 Rev.01	2017-07-06	2024-05-26
Washing Pipe for Single Use	PW-A, PW-B	15198	IIa, Rule 5	Annex II, excluding 4	G1 039452 0033 Rev.01	2017-07-06	2024-05-26
Hot Biopsy forceps for single use	FD-A, FD-B	61455	IIa, Rule 6	Annex II, excluding 4	G1 039452 0033 Rev.01	2017-07-06	2024-05-26
Cytology Brushes for single use	BC-L-24,BC-L-18, BC-U-24, BC-U-18	15018	I Sterile, Rule 5	Annex V	G2S 039452 0032 Rev.02	2010-12-13	2024-05-26
Mouth Guards for single use	MG-A1, MG-A2, MG-B1, MG-B2	16366	I Sterile, Rule 5	Annex V	G2S 039452 0032 Rev.02	2010-12-13	2024-05-26
Biopsy Valve for Single Use	BV-A,BV-B	14325	I Sterile, Rule 1	Annex V	G2S 039452 0032 Rev.02	2017-07-06	2024-05-26

Certification Notify Body：

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstrasse 65 · 80339 München · Germany 0123

Content of Declaration：

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

Directives：

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical device (MDD/93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007.

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www.kangjin.cn

According to appendix VII Directive 93/42/EEC, we declare that the Medical Devices Class I according to appendix IX Directive 93/42/EEC with the description

1) **BRUSH FOR ENDOSCOPY CLEANING** which made of PA Nylon, POM or stainless conform in all aspects to those mentioned on appendix I Directive 93/42/EEC,
2) **Multi-Chamber Polyp Traps** which made of PC, PP and PVC conform in all aspects to those mentioned on appendix II Directive 93/42/EEC, excluding section 4.

Issue place and date: Changzhou, 2019-05-27

JIANGSU KANGJIN MEDICAL INSTRUMENT CO., LTD.

Signature:
Name: Xiaocheng Ye
Position: General Manager

President

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