EU Declaration of Conformity

Doc.No.KX-QS9.3.a-SDPT0203-R-ASI240523 Rev.00

Manufacturer:	**Wujiang Kangxin Surgical Dressings Co., Ltd.** No. 1309 Jinshe Road, Jinjiaba Town, 215215 Wujiang City, Jiangsu Province, PEOPLE’S REPUBLIC OF CHINA	SRN No.:	CN-MF-000012611
European Representative:	**Shanghai International Holding Corp.GmbH(Europe)** Eiffestra β e 80, 20537 Hamburg GERMANY	SRN No.:	DE-AR-000000001
EMDN code:	T0203	GMDN code:	61355
Product Name	Sterile Urethral Catheterization Support Pack		
REF code	With reference to Annex 1 Product Information		

Classification (MDR, Annex VIII): Class I Sterile
Conformity Assessment Route: Annex IX Part A

We herewith declare that this EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.The products above are in conformity with the Medical Device Regulation (EU) 2017/745.All supporting documentation is retained under the premises of the manufacturer. **Wujiang Kangxin Surgical Dressings Co., Ltd** is responsible for this EU Declaration of Conformity.

General Applicable Regulation:
Medical Device Regulation (EU) 2017/745 and other applicable EU standards and MDCG Guidance.

Notified Body:	**TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany**
Identification number:	CE0123
(EC) Certificate(s):	G21 060968 0018Rev.00
Expire date of the Certificate:	2028-12-14
Place, Date of Issue:	Wujiang,2024-05-23

Wujiang Kangxin Surgical Dressings Co., Ltd.

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Annex I Product Information

Trade Name	Kangxin REF Code	Trade REF Code	Basic UDI-DI	Classification Rule
Balloon catheter exchange set	KX-SDP02010101	S-010000	697262114SDP02010101N5	Rule 1
Balloon catheter exchange set	KX-SDP02010102	S-020000-N	697262114SDP02010102N7	Rule 1
Balloon catheter exchange set	KX-SDP02010103	S-030000	697262114SDP02010103N9	Rule 1
Balloon catheter exchange set	KX-SDP02010104	S-030000-N	697262114SDP02010104NB	Rule 1
Balloon catheter exchange set	KX-SDP02010106	S-030000-P-N	697262114SDP02010106NF	Rule 1
Balloon catheter exchange set	KX-SDP02010107	S-040000	697262114SDP02010107NH	Rule 1
Balloon catheter exchange set	KX-SDP02010108	S-050000	697262114SDP02010108NK	Rule 1
Balloon catheter exchange set	KX-SDP02010109	S-060000	697262114SDP02010109NM	Rule 1
Balloon catheter exchange set	KX-SDP02010110	S-060000-N	697262114SDP02010110N6	Rule 1
Balloon catheter exchange set	KX-SDP02010111	S-070000	697262114SDP02010111N8	Rule 1

Name: Michelle Zhang Signature: Michelle·Z Position: PRRC

Document Reference	Document Name	Designed by	Approved By	Revision Number	Issue Date
KX-QS9.3.a	EU Declaration of Conformity	Ruby Fu	Michelle Zhang	00	2023-06-20