

 CE MDR Technical Documentation	EU Declaration of Conformity	Document No.	TDSSK-CE-00-01
		Edition	C2
		Effective Date	2023-07-20
		Page No.	Page 1 of 2

Sterile Disposable Skin Stapler

Basic UDI-DI: 6947084900014AA

Edition Number: C2

Revised Number:

Be Controlled:

Distribute Number:

Compiled by: Bochao Zhasi

Date: 2023.07.20

Reviewed by: Wenjia Li

Date: 2023.07.20

Approved by: Bai Zhao Xia

Date: 2023.07.20

Xi'an Kaydee Medical Appliances Co., Ltd

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		Page No.	Page 2 of 2

EU Declaration of Conformity

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

MANUFACTURER:

Name: Xi'an Kaydee Medical Appliances Co., Ltd.
 Address: 10101, Building 6, No.299 Second Industrial Road, Space Base, 710100 Xi'an, PEOPLE'S
 REPUBLIC OF CHINA
 SRN: CN-MF-000021140

EUROPEAN REPRESENTATIVE:

Name: MedPath GmbH
 Address: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany
 SRN: DE-AR-000000087

MEDICAL DEVICE:

Product Name: Sterile Disposable Skin Stapler

Trade Name: 

Product Type: SSK-10W, SSK-15W, SSK-20W, SSK-25W, SSK-30W, SSK-35W, SSK-40W, SSK-45W, SSK-50W, SSK-55W,
 SSK-10R, SSK-15R, SSK-20R, SSK-25R, SSK-30R, SSK-35R, SSK-40R, SSK-45R, SSK-50R, SSK-55R

Basic UDI-DI: 6947084900014AA

EMDN Code: H02010101

Classification acc. to MDR Ax. VIII: Class IIa, Rule 7

Conformity assessment procedure: Regulation (EU) 2017/745 Annex XI, Part A

We here with declare in our own responsibility that the above-mentioned product meets the provisions of the Medical Device Regulation 2017/745. All supporting documentation is retained under the premises of the manufacturer (head of Quality department). The declaration of conformity is issued under our sole responsibility.

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany
 NB Identification number: 0123
 CE Certificate No: G20 061912 0016 Rev.00
 Expire date of the Certificate: 2028-07-19
 Start of CE Marking: 2023-07-20

Place issue: Xi'an, P. R. China

Date of issue: 2023-07-20

Signature:


 Ms. Bai Zhaoxia

Position: PRRC