# Sterile Disposable Staple Remover

Basic UDI-DI: 6947084900021A7

Edition Number: C0

Revised Number:

Be Controlled:

Distribute Number:

Compiled by: Bochao Zhai 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

# EU Declaration of Conformity

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

**MANUFACTURER:**

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|---|---|
| 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:**

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

**MEDICAL DEVICE:**

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|---|---|
| Product Name: | Sterile Disposable Staple Remover |
| Trade Name: | Kaydee® |
| Product Type： | SRK-T-1, SRK-T-2, SRK-T-3, SRK-T-4, SRK-T-5. |
| Basic UDI-DI: | 6947084900021A7 |
| EMDN Code： | H02010106 |
| Classification acc. to MDR Ax. VIII: | **I* sterile, Rule 1** |
| 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.

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| Notified Body: | TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany |
| NB Identification number: | 0123 |
| CE Certificate No: | G21 061912 0017 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:**

Zhao Xia Bai
Ms. Bai Zhaoxia

**Position:** PRRC