



kai industries co., ltd.

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DECLARATION OF CONFORMITY

Product Group: Dermatological Instruments
 General Product Group: Biopsy Punches
 Product Name: Dermal Curette

Product List: See the attached CE Marked Product List

Product Lot. No.: See the shipping records
 (This documentation is maintained by Kai Industries Co., Ltd.)

MDD-Classification: Class IIa (Applied the Rule 6, Subclause 1, No Indent)

Applied Standards: See the attached Document I

Manufacturer (SRN): Kai Industries Co., Ltd. (To Be Confirmed)
 1110 Oyana, Seki City, Gifu Pref., 501-3992, JAPAN

Authorized European Representative (SRN): Kai Europe GmbH (DE-AR-000005096)
 Kottendorfer Straße 5, 42697 Solingen, GERMANY

The undersigned hereby declares that the medical device as specified above conforms to the essential requirements listed in Annex I and II of the European Medical Device Directive 93/42/EEC (MDD).

This declaration of conformity is based on

The European Medical Device Directive 93/42/EEC Annex II and is supported by a TÜV Rheinland LGA Products GmbH Notified Body (0197) Annex II Approval, with reference to articles 1 and 3 of the MDD (TÜV Rheinland LGA Products GmbH (Tillystraße 2, 90431 Nürnberg, GERMANY) Approval Registration No. HD 60148506 0001).

This Declaration of Conformity is valid in connection with the shipping records for the respective lot number of produced medical devices.

Place and Date of issue: Seki, August 6, 2021

Makoto Mori
 Senior Corporate Officer,
 Kai Industries Co., Ltd.

Attached Document I : List of applied standards

- **EN ISO 13485:2016**
- **EN ISO 13485:2016/AC:2018**
Medical devices - Quality management systems - Requirements for regulatory purposes
- **EN ISO 14971:2012**
Medical devices - Application of risk management to medical devices
- **EN 1041:2008+A1:2013**
Information supplied by the manufacturer of medical devices
- **EN ISO 15223-1:2016**
Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
- **EN ISO 10993-1:2009/AC:2010**
Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- **EN 556-1:2001/AC:2006**
Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE' - Part 1: Requirements for terminally sterilized medical devices
- **EN ISO 11607-1:2009+A1:2014**
Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- **EN ISO 11607-2:2006+A1:2014**
Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- **EN ISO 11137-1:2015/A2:2019**
Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- **EN ISO 11137-2:2015**
Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
- **EN ISO 11737-1:2006 /AC:2009**
Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
- **EN ISO 11737-2:2009**
Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- **EN 62366:2008**
Medical devices - Application of usability engineering to medical devices
- **ISO 14644-1:2015**
Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness

CE Marked Product List - Biopsy Punches - Dermal Curette

Revision No. / Date: Rev.1 / 2021-08-06

EC Certificate Registration No.: HD 60148506 0001

General Product Group: Biopsy Punches

Sterilization Method: Gamma radiation

Classification: Class IIa (Rule 6)

UMDNS Number: 13-230

Allocation of all Products into Device Subcategories According to NBOG BPG 2009-3: MD0106

Declaration of Conformity initial Issue Date / Latest Revision: 2021-08-06 / N/A (Rev.1)

Technical Documentation Issue Date/ Rev.: KH-M-TF-04-R 2021-08-06 / Rev.16

Legal Manufacturer: Kai Industries Co., Ltd.

Manufacturing Facility: Kai Industries Co., Ltd. Oyana factory

Sterilization Facility: KOGA ISOTOPE LIMITED

R&D Facility: Kai Industries Co., Ltd. Oyana factory

European Representative: Kai Europe GmbH

Signature: 
 Approved by: Makoto Mori, Senior Corporate Officer

| Catalogue No. (REF No.) | Description | UDI-DI Primary package | UDI-DI Secondary package |
|----------------------------|-------------------------------|---------------------------|-----------------------------|
| MK402 | DISPOSABLE DERMAL CURETTE 2mm | 04560146922230 | 14560146922237 |
| MK403 | DISPOSABLE DERMAL CURETTE 3mm | 04560146922223 | 14560146922220 |
| MK404 | DISPOSABLE DERMAL CURETTE 4mm | 04560146922209 | 14560146922206 |
| MK405 | DISPOSABLE DERMAL CURETTE 5mm | 04560146922216 | 14560146922213 |
| MK407 | DISPOSABLE DERMAL CURETTE 7mm | 04560146922247 | 14560146922244 |
| LCH-CUK-20 | DISPOSABLE DERMAL CURETTE 2mm | 04560146925446 | 14560146925443 |
| LCH-CUK-30 | DISPOSABLE DERMAL CURETTE 3mm | 04560146925453 | 14560146925450 |
| LCH-CUK-40 | DISPOSABLE DERMAL CURETTE 4mm | 04560146925460 | 14560146925467 |
| LCH-CUK-50 | DISPOSABLE DERMAL CURETTE 5mm | 04560146925477 | 14560146925474 |
| LCH-CUK-70 | DISPOSABLE DERMAL CURETTE 7mm | 04560146925484 | 14560146925481 |
| 50102 | DISPOSABLE DERMAL CURETTE 2mm | 04560146926498 | 14560146926495 |
| 50103 | DISPOSABLE DERMAL CURETTE 3mm | 04560146926504 | 14560146926501 |
| 50104 | DISPOSABLE DERMAL CURETTE 4mm | 04560146926511 | 14560146926518 |
| 50105 | DISPOSABLE DERMAL CURETTE 5mm | 04560146926528 | 14560146926525 |
| 50107 | DISPOSABLE DERMAL CURETTE 7mm | 04560146926535 | 14560146926532 |