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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. (JP-MF-000016663) 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-shi, Gifu 501-3992, Japan August 17, 2023

Makoto Mori
Director,
Kai Industries Co., Ltd.

Attached Document I : List of applied standards

- **EN ISO 13485:2016**
- **EN ISO 13485:2016/A11:2021**
  Medical devices - Quality management systems - Requirements for regulatory purposes
- **EN ISO 14971:2019+A11:2021**
  Medical devices - Application of risk management to medical devices
- **EN ISO 20417:2021**
  Medical devices - Information to be provided by the manufacturer
- **EN ISO 15223-1:2021**
  Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
- **EN ISO 10993-1:2020**
  Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- **EN ISO 10993-5:2009**
  Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- **EN ISO 10993-10:2021**
  Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- **EN ISO 10993-11:2017**
  Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- **EN ISO 10993-23:2021**
  Biological evaluation of medical devices - Part 23: Tests for irritation
- **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 11607-1:2020/A11:2022**
  Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- **EN ISO 11607-2:2020/A11:2022**
  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/A1:2023**
  Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
- **EN ISO 11737-1:2018/A1:2021**
  Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
- **EN ISO 11737-2:2020**
  Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- **EN 62366-1:2015+A1:2020**
  Medical devices - Application of usability engineering to medical devices
- **ISO 14644-1:2015**
  Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness

- **MDCG 2020-5**
  Clinical Evaluation – Equivalence, A guide for manufacturers and notified bodies, April 2020
- **MDCG 2020-6**
  Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC, A guide for manufacturers and notified bodies, April 2020
- **MDCG 2020-7**
  Post-market clinical follow-up (PMCF) Plan Template, A guide for manufacturers and notified bodies, April 2020
- **MDCG 2020-8**
  Post-market clinical follow-up (PMCF) Evaluation Report Template, A guide for manufacturers and notified bodies, April 2020

CE Marked Product List - Biopsy Punches - Dermal Curette

Revision No. / Date: Rev.6 / 2023-08-17
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 / 2023-08-17 (Rev.4)
Technical Documentation Issue Date/ Rev.: KH-M-TF-04-R 2023-08-17 / Rev.21
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
Authorized European Representative: Kai Europe GmbH

Signature: Makoto Mori
Approved by: Makoto Mori, Director

Catalogue No. (REF No.)	Description	UDI-DI Primary package	UDI-DI Secondary package
MK402	DERMAL CURETTE 2mm	04560146928461	14560146928468
MK403	DERMAL CURETTE 3mm	04560146928478	14560146928475
MK404	DERMAL CURETTE 4mm	04560146928485	14560146928482
MK405	DERMAL CURETTE 5mm	04560146928492	14560146928499
MK407	DERMAL CURETTE 7mm	04560146928508	14560146928505
LCH-CUK-20	DERMAL CURETTE 2mm	04560146928904	14560146928901
LCH-CUK-30	DERMAL CURETTE 3mm	04560146928911	14560146928918
LCH-CUK-40	DERMAL CURETTE 4mm	04560146928928	14560146928925
LCH-CUK-50	DERMAL CURETTE 5mm	04560146928935	14560146928932
LCH-CUK-70	DERMAL CURETTE 7mm	04560146928942	14560146928949
50102	DERMAL CURETTE 2mm	04562143740213	14562143740210
50103	DERMAL CURETTE 3mm	04562143740220	14562143740227
50104	DERMAL CURETTE 4mm	04562143740237	14562143740234
50105	DERMAL CURETTE 5mm	04562143740244	14562143740241
50107	DERMAL CURETTE 7mm	04562143740251	14562143740258