kai medical

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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: Makoto Mori
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