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DECLARATION OF CONFORMITY

for DERMAL CURETTE

This EU declaration of conformity is issued under the sole responsibility of the manufacturer as follows.

Product Family (EMDN Code):	Level 4: CUTANEOUS BIOPSY NEEDLES AND KITS (A010203) Lowest level: CUTANEOUS BIOPSY CURETTES, SINGLE-USE (A01020303)
Basic UDI-DI:	456014692AC014T
Product Name:	DERMAL CURETTE
Classification:	Class IIa (Annex VIII, Rule 6)
Intended Purpose:	To curette skin tissue for the examination, diagnosis and treatment of skin disease.
Applied Standards:	See the attached Document I
Product List:	See the attached CE Marked Product List
Product Lot. No.:	See the shipping records (The documentation is maintained by the manufacturer)
Manufacturer (SRN):	Kai Industries Co., Ltd. (JP-MF-000016663) 1110 Oyana, Seki-shi, Gifu 501-3992, Japan
Authorised 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 provisions of the European Medical Device Regulation 2017/745 (MDR).

This declaration of conformity is based on MDR Annex IV and IX and is supported by TÜV Rheinland LGA Products GmbH Notified Body (0197) Annex IX Approval. The certificate No. from TÜV Rheinland LGA Products GmbH (Tillystraße 2, 90431 Nürnberg, Germany) is HZ 2066395-1.

Signed for and on behalf of Kai Industries Co., Ltd. at 1110 Oyana, Seki-shi, Gifu 501-3992, Japan

Date of issue: December 16th, 2024

Makoto Mori
Director

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 supplied 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 10993-10:2023**
  Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- **EN ISO 10993-11:2018**
  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/A1:2023**
  Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems - Amendment 1: Application of risk management
- **EN ISO 11607-2:2020/A1:2023**
  Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes - Amendment 1: Application of risk management
- **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 - Amendment 2: Revision to 4.3.4 and 11.2
- **EN ISO 11137-2:2015/A1:2023**
  Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose - Amendment 1
- **EN ISO 11737-1:2018/A1:2021**
  Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products - Amendment 1
- **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 - Part 1: Application of usability engineering to medical devices

- **ISO 14644-1:2015**
  Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration

- **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

- **Recommendation NB-MED/2.5.1/Rec5**
  Technical Documentation

CE Marked Product List - DERMAL CURETTE

Revision No. / Date: Rev.7 / 2024-12-16
Declaration of Conformity initial Issue Date / Latest Revision: 2021-08-06 / 2024-12-16 (Rev.5)

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