



# KAI INDUSTRIES CO., LTD.

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## DECLARATION OF CONFORMITY for BIOPSY PUNCH

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)<br>Lowest level: CUTANEOUS BIOPSY PUNCHES, SINGLE-USE (A01020302)  |
| Basic UDI-DI:                    | 456014692AB014N   |
| Product Name:                    | BIOPSY PUNCH  |
| Classification:                  | Class IIa (Annex VIII, Rule 6)  |
| Intended Purpose:                | To perforate and collect skin tissues. The collected tissues are used for examination, treatment, and diagnosis of patients with skin tumors and other skin diseases. |
| Applied Standards:               | See the attached Document I   |
| Product List:                    | See the attached CE Marked Product List   |
| Product Lot. No.:                | See the shipping records<br>(The documentation is maintained by the manufacturer)   |
| Manufacturer (SRN):              | Kai Industries Co., Ltd. (JP-MF-000016663)<br>1110 Oyana, Seki-shi, Gifu 501-3992, Japan  |
| Authorised Representative (SRN): | Kai Europe GmbH (DE-AR-000005096)<br>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 16<sup>th</sup>, 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