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) 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 (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 - BIOPSY PUNCH

Revision No. / Date: Rev.17 / 2024-12-16
Declaration of Conformity initial Issue Date / Latest Revision: 1996-10-01 / 2024-12-16 (Rev.34)

Signature: Makoto Mori
Approved by: Makoto Mori, Director

Catalogue No. (REF No.)	Description	UDI-DI Primary package	UDI-DI Secondary package
BP-10F	BIOPSY PUNCH 1mm	04560146928515	14560146928512
BP-15F	BIOPSY PUNCH 1.5mm	04560146928539	14560146928536
BP-20F	BIOPSY PUNCH 2mm	04560146928546	14560146928543
BP-25F	BIOPSY PUNCH 2.5mm	04560146928522	14560146928529
BP-30F	BIOPSY PUNCH 3mm	04560146928553	14560146928550
BP-35F	BIOPSY PUNCH 3.5mm	04560146928560	14560146928567
BP-40F	BIOPSY PUNCH 4mm	04560146928577	14560146928574
BP-50F	BIOPSY PUNCH 5mm	04560146928584	14560146928581
BP-60F	BIOPSY PUNCH 6mm	04560146928591	14560146928598
BP-80F	BIOPSY PUNCH 8mm	04560146928607	14560146928604
BPP-10F	BIOPSY PUNCH 1mm with Plunger	04560146928614	14560146928611
BPP-15F	BIOPSY PUNCH 1.5mm with Plunger	04560146928621	14560146928628
BPP-20F	BIOPSY PUNCH 2mm with Plunger	04560146928638	14560146928635
BPP-30F	BIOPSY PUNCH 3mm with Plunger	04560146928645	14560146928642
BPP-40F	BIOPSY PUNCH 4mm with Plunger	04560146928652	14560146928659
BP-10F	BIOPSY PUNCH 1mm (SMS)	04560146929055	14560146929052
BP-15F	BIOPSY PUNCH 1.5mm (SMS)	04560146929062	14560146929069
BP-20F	BIOPSY PUNCH 2mm (SMS)	04560146929079	14560146929076
BP-25F	BIOPSY PUNCH 2.5mm (SMS)	04560146929086	14560146929083
BP-30F	BIOPSY PUNCH 3mm (SMS)	04560146929093	14560146929090
BP-35F	BIOPSY PUNCH 3.5mm (SMS)	04560146929109	14560146929106
BP-40F	BIOPSY PUNCH 4mm (SMS)	04560146929116	14560146929113
BP-50F	BIOPSY PUNCH 5mm (SMS)	04560146929123	14560146929120

Catalogue No. (REF No.)	Description	UDI-DI Primary package	UDI-DI Secondary package
BP-60F	BIOPSY PUNCH 6mm (SMS)	04560146929130	14560146929137
BP-80F	BIOPSY PUNCH 8mm (SMS)	04560146929147	14560146929144
BPP-10F	BIOPSY PUNCH 1mm with Plunger (SMS)	04560146929154	14560146929151
BPP-15F	BIOPSY PUNCH 1.5mm with Plunger (SMS)	04560146929161	14560146929168
BPP-20F	BIOPSY PUNCH 2mm with Plunger (SMS)	04560146929178	14560146929175
BPP-30F	BIOPSY PUNCH 3mm with Plunger (SMS)	04560146929185	14560146929182
BPP-40F	BIOPSY PUNCH 4mm with Plunger (SMS)	04560146929192	14560146929199
LCH-PUK-10	BIOPSY PUNCH 1mm	04560146928959	14560146928956
LCH-PUK-15	BIOPSY PUNCH 1.5mm	04560146928966	14560146928963
LCH-PUK-20	BIOPSY PUNCH 2mm	04560146928973	14560146928970
LCH-PUK-25	BIOPSY PUNCH 2.5mm	04560146928980	14560146928987
LCH-PUK-30	BIOPSY PUNCH 3mm	04560146928997	14560146928994
LCH-PUK-35	BIOPSY PUNCH 3.5mm	04560146929000	14560146929007
LCH-PUK-40	BIOPSY PUNCH 4mm	04560146929017	14560146929014
LCH-PUK-50	BIOPSY PUNCH 5mm	04560146929024	14560146929021
LCH-PUK-60	BIOPSY PUNCH 6mm	04560146929031	14560146929038
LCH-PUK-80	BIOPSY PUNCH 8mm	04560146929048	14560146929045
48101	BIOPSY PUNCH 1mm	04560146929277	14560146929274
48115	BIOPSY PUNCH 1.5mm	04560146929284	14560146929281
48201	BIOPSY PUNCH 2mm	04560146929208	14560146929205
48251	BIOPSY PUNCH 2.5mm	04560146929291	14560146929298
48301	BIOPSY PUNCH 3mm	04560146929215	14560146929212
48351	BIOPSY PUNCH 3.5mm	04560146929260	14560146929267
48401	BIOPSY PUNCH 4mm	04560146929222	14560146929229
48501	BIOPSY PUNCH 5mm	04560146929239	14560146929236
48601	BIOPSY PUNCH 6mm	04560146929246	14560146929243
48801	BIOPSY PUNCH 8mm	04560146929253	14560146929250
49101	BIOPSY PUNCH 1mm with Plunger	04560146929307	14560146929304

Catalogue No. (REF No.)	Description	UDI-DI Primary package	UDI-DI Secondary package
49115	BIOPSY PUNCH 1.5mm with Plunger	04560146929314	14560146929311
49201	BIOPSY PUNCH 2mm with Plunger	04560146929321	14560146929328
49301	BIOPSY PUNCH 3mm with Plunger	04560146929338	14560146929335
49401	BIOPSY PUNCH 4mm with Plunger	04560146929345	14560146929342