



kai industries co., ltd.

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DECLARATION OF CONFORMITY

Product Group: Dermatological Instruments
 General Product Group: Biopsy Punches
 Product Name: Biopsy Punch

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

A handwritten signature in black ink, appearing to read 'Makoto Mori', written over a horizontal line.

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 - Biopsy Punch

Revision No. / Date: Rev.9 / 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: 1996-10-01 / 2021-08-06 (Rev.29)

Technical Documentation Issue Date/ Rev.: KH-M-TF-05-R 2021-08-06 / Rev.10

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: 

Approved by: Makoto Mori, Senior Corporate Officer

Catalogue No. (REF No.)	Description	UDI-DI Primary package	UDI-DI Secondary package
BP-10F	DISPOSABLE BIOPSY PUNCH 1.0mm	04560146923053	14560146923050
BP-15F	DISPOSABLE BIOPSY PUNCH 1.5mm	04560146922629	14560146922626
BP-20F	DISPOSABLE BIOPSY PUNCH 2.0mm	04560146922605	14560146922602
BP-25F	DISPOSABLE BIOPSY PUNCH 2.5mm	04560146923060	14560146923067
BP-30F	DISPOSABLE BIOPSY PUNCH 3.0mm	04560146922599	14560146922596
BP-35F	DISPOSABLE BIOPSY PUNCH 3.5mm	04560146922551	14560146922558
BP-40F	DISPOSABLE BIOPSY PUNCH 4.0mm	04560146922582	14560146922589
BP-50F	DISPOSABLE BIOPSY PUNCH 5.0mm	04560146922612	14560146922619
BP-60F	DISPOSABLE BIOPSY PUNCH 6.0mm	04560146922575	14560146922572
BP-80F	DISPOSABLE BIOPSY PUNCH 8.0mm	04560146922568	14560146922565
BP-L15K	DISPOSABLE BIOPSY PUNCH 1.5mm (LONG TYPE)	04560146922797	14560146922794
BP-L20K	DISPOSABLE BIOPSY PUNCH 2.0mm (LONG TYPE)	04560146922858	14560146922855
BP-L30K	DISPOSABLE BIOPSY PUNCH 3.0mm (LONG TYPE)	04560146922841	14560146922848
BP-L35K	DISPOSABLE BIOPSY PUNCH 3.5mm (LONG TYPE)	04560146922834	14560146922831
BP-L40K	DISPOSABLE BIOPSY PUNCH 4.0mm (LONG TYPE)	04560146922483	14560146922480
BP-L50K	DISPOSABLE BIOPSY PUNCH 5.0mm (LONG TYPE)	04560146922827	14560146922824

Catalogue No. (REF No.)	Description	UDI-DI Primary package	UDI-DI Secondary package
BP-L60K	DISPOSABLE BIOPSY PUNCH 6.0mm (LONG TYPE)	04560146922810	14560146922817
BP-L80K	DISPOSABLE BIOPSY PUNCH 8.0mm (LONG TYPE)	04560146922803	14560146922800
BPP-10F	DISPOSABLE BIOPSY PUNCH WITH PLUNGER SYSTEM 1.0mm	04560146924531	14560146924538
BPP-15F	DISPOSABLE BIOPSY PUNCH WITH PLUNGER SYSTEM 1.5mm	04560146924548	14560146924545
BPP-20F	DISPOSABLE BIOPSY PUNCH WITH PLUNGER SYSTEM 2.0mm	04560146924555	14560146924552
BPP-30F	DISPOSABLE BIOPSY PUNCH WITH PLUNGER SYSTEM 3.0mm	04560146924838	14560146924835
BPP-40F	DISPOSABLE BIOPSY PUNCH WITH PLUNGER SYSTEM 4.0mm	04560146924845	14560146924842
BP-10F	DISPOSABLE BIOPSY PUNCH 1.0mm (SMS)	04560146927624	14560146927621
BP-15F	DISPOSABLE BIOPSY PUNCH 1.5mm (SMS)	04560146927631	14560146927638
BP-20F	DISPOSABLE BIOPSY PUNCH 2.0mm (SMS)	04560146927648	14560146927645
BP-25F	DISPOSABLE BIOPSY PUNCH 2.5mm (SMS)	04560146927655	14560146927652
BP-30F	DISPOSABLE BIOPSY PUNCH 3.0mm (SMS)	04560146927662	14560146927669
BP-35F	DISPOSABLE BIOPSY PUNCH 3.5mm (SMS)	04560146927679	14560146927676
BP-40F	DISPOSABLE BIOPSY PUNCH 4.0mm (SMS)	04560146927686	14560146927683
BP-50F	DISPOSABLE BIOPSY PUNCH 5.0mm (SMS)	04560146927693	14560146927690
BP-60F	DISPOSABLE BIOPSY PUNCH 6.0mm (SMS)	04560146927709	14560146927706
BP-80F	DISPOSABLE BIOPSY PUNCH 8.0mm (SMS)	04560146927716	14560146927713
BPP-10F	DISPOSABLE BIOPSY PUNCH WITH PLUNGER SYSTEM 1.0mm (SMS)	04560146927723	14560146927720
BPP-15F	DISPOSABLE BIOPSY PUNCH WITH PLUNGER SYSTEM 1.5mm (SMS)	04560146927730	14560146927737
BPP-20F	DISPOSABLE BIOPSY PUNCH WITH PLUNGER SYSTEM 2.0mm (SMS)	04560146927747	14560146927744
BPP-30F	DISPOSABLE BIOPSY PUNCH WITH PLUNGER SYSTEM 3.0mm (SMS)	04560146927754	14560146927751
BPP-40F	DISPOSABLE BIOPSY PUNCH WITH PLUNGER SYSTEM 4.0mm (SMS)	04560146927761	14560146927768
48101	DISPOSABLE BIOPSY PUNCH 1.0mm	04560146924999	14560146924996
48115	DISPOSABLE BIOPSY PUNCH 1.5mm	04560146924579	14560146924576
48201	DISPOSABLE BIOPSY PUNCH 2.0mm	04560146923251	14560146923258
48251	DISPOSABLE BIOPSY PUNCH 2.5mm	04560146927242	14560146927249
48301	DISPOSABLE BIOPSY PUNCH 3.0mm	04560146923244	14560146923241
48351	DISPOSABLE BIOPSY PUNCH 3.5mm	04560146923367	14560146923364

Catalogue No. (REF No.)	Description	UDI-DI Primary package	UDI-DI Secondary package
48401	DISPOSABLE BIOPSY PUNCH 4.0mm	04560146923237	14560146923234
48501	DISPOSABLE BIOPSY PUNCH 5.0mm	04560146923220	14560146923227
48601	DISPOSABLE BIOPSY PUNCH 6.0mm	04560146923213	14560146923210
48801	DISPOSABLE BIOPSY PUNCH 8.0mm	04560146923206	14560146923203
49101	DISPOSABLE BIOPSY PUNCH WITH PLUNGER SYSTEM 1.0mm	04560146924944	14560146924941
49115	DISPOSABLE BIOPSY PUNCH WITH PLUNGER SYSTEM 1.5mm	04560146924951	14560146924958
49201	DISPOSABLE BIOPSY PUNCH WITH PLUNGER SYSTEM 2.0mm	04560146924968	14560146924965
49301	DISPOSABLE BIOPSY PUNCH WITH PLUNGER SYSTEM 3.0mm	04560146924975	14560146924972
49401	DISPOSABLE BIOPSY PUNCH WITH PLUNGER SYSTEM 4.0mm	04560146924982	14560146924989
LCH-PUK-10	DISPOSABLE BIOPSY PUNCH 1.0mm	04560146925347	14560146925344
LCH-PUK-15	DISPOSABLE BIOPSY PUNCH 1.5mm	04560146925354	14560146925351
LCH-PUK-20	DISPOSABLE BIOPSY PUNCH 2.0mm	04560146925361	14560146925368
LCH-PUK-25	DISPOSABLE BIOPSY PUNCH 2.5mm	04560146925378	14560146925375
LCH-PUK-30	DISPOSABLE BIOPSY PUNCH 3.0mm	04560146925385	14560146925382
LCH-PUK-35	DISPOSABLE BIOPSY PUNCH 3.5mm	04560146925392	14560146925399
LCH-PUK-40	DISPOSABLE BIOPSY PUNCH 4.0mm	04560146925408	14560146925405
LCH-PUK-50	DISPOSABLE BIOPSY PUNCH 5.0mm	04560146925415	14560146925412
LCH-PUK-60	DISPOSABLE BIOPSY PUNCH 6.0mm	04560146925422	14560146925429
LCH-PUK-80	DISPOSABLE BIOPSY PUNCH 8.0mm	04560146925439	14560146925436