kai medical

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DECLARATION OF CONFORMITY

Product Group:	Dermatological Instruments
General Product Group:	Biopsy Punches
Product Name:	1) Biopsy Punch 2) Dermal Curette 3) Biopsiblade
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:	Kai Industries Co., Ltd. 1110 Oyana, Seki City, Gifu Pref., 501-3992, JAPAN
Authorized European Representative:	Kai Europe GmbH Kottendorfer Straße 5, 42697 Solingen, GERMANY

The undersigned hereby declares that the medical device as specified above conforms to the essential requirements listed in the 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, October 21, 2020

Makoto Mori

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:2016**
  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 ISO 10993-7:2008/AC:2009**
  Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
- **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 11135:2014**
  Sterilization of health care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
- **EN ISO 11137-1:2015**
  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 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

Revision No. / Date : Rev.8/ 2020-10-21
EC Certificate Registration No. : HD 60148506 0001
General Product Group : Biopsy Punches
Classification : Class IIa (Rule 6)
UMDNS Number : 13-230
Legal Manufacturer : Kai Industries Co., Ltd.
Manufacturing Facility : Kai Industries Co., Ltd. Oyana factory
R&D Facility : Kai Industries Co., Ltd. Oyana factory
European Representative : Kai Europe GmbH
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 / 2020-10-21 (Rev.28)

Signature: Makoto Mori
Approved by: Makoto Mori, Senior Corporate Officer

A. Sterilization Method : EOG Sterilization Facility : Kai Industries Co., Ltd. Oyana factory

Catalogue No. (REF No.)	Description	Technical Documentation Issue Date/ Rev.
Product Name: Biopsiblade		
BB-01	BIOPSIBLADE	KH-M-TF-06-E 2020-10-21 / Rev.19

B. Sterilization Method: Gamma radiation Sterilization Facility: KOGA ISOTOPE LIMITED

Catalogue No. (REF No.)	Description	Technical Documentation Issue Date/ Rev.
Product Name: Biopsy Punch		
BP-10F	DISPOSABLE BIOPSY PUNCH 1.0mm	KH-M-TF-05-R 2020-10-21 / Rev.9
BP-15F	DISPOSABLE BIOPSY PUNCH 1.5mm	KH-M-TF-05-R 2020-10-21 / Rev.9
BP-20F	DISPOSABLE BIOPSY PUNCH 2.0mm	KH-M-TF-05-R 2020-10-21 / Rev.9
BP-25F	DISPOSABLE BIOPSY PUNCH 2.5mm	KH-M-TF-05-R 2020-10-21 / Rev.9
BP-30F	DISPOSABLE BIOPSY PUNCH 3.0mm	KH-M-TF-05-R 2020-10-21 / Rev.9
BP-35F	DISPOSABLE BIOPSY PUNCH 3.5mm	KH-M-TF-05-R 2020-10-21 / Rev.9
BP-40F	DISPOSABLE BIOPSY PUNCH 4.0mm	KH-M-TF-05-R 2020-10-21 / Rev.9
BP-50F	DISPOSABLE BIOPSY PUNCH 5.0mm	KH-M-TF-05-R 2020-10-21 / Rev.9
BP-60F	DISPOSABLE BIOPSY PUNCH 6.0mm	KH-M-TF-05-R 2020-10-21 / Rev.9
BP-80F	DISPOSABLE BIOPSY PUNCH 8.0mm	KH-M-TF-05-R 2020-10-21 / Rev.9
BP-L15K	DISPOSABLE BIOPSY PUNCH L1.5mm(LONG TYPE)	KH-M-TF-05-R 2020-10-21 / Rev.9
BP-L20K	DISPOSABLE BIOPSY PUNCH L2.0mm(LONG TYPE)	KH-M-TF-05-R 2020-10-21 / Rev.9

Catalogue No. (REF No.)	Description	Technical Documentation Issue Date/ Rev.
BP-L30K	DISPOSABLE BIOPSY PUNCH L3.0mm (LONG TYPE)	KH-M-TF-05-R 2020-10-21 / Rev.9
BP-L35K	DISPOSABLE BIOPSY PUNCH L3.5mm (LONG TYPE)	KH-M-TF-05-R 2020-10-21 / Rev.9
BP-L40K	DISPOSABLE BIOPSY PUNCH L4.0mm (LONG TYPE)	KH-M-TF-05-R 2020-10-21 / Rev.9
BP-L50K	DISPOSABLE BIOPSY PUNCH L5.0mm (LONG TYPE)	KH-M-TF-05-R 2020-10-21 / Rev.9
BP-L60K	DISPOSABLE BIOPSY PUNCH L6.0mm (LONG TYPE)	KH-M-TF-05-R 2020-10-21 / Rev.9
BP-L80K	DISPOSABLE BIOPSY PUNCH L8.0mm (LONG TYPE)	KH-M-TF-05-R 2020-10-21 / Rev.9
BPP-10F	DISPOSABLE BIOPSY PUNCH WITH PLUNGER SYSTEM 1.0mm	KH-M-TF-05-R 2020-10-21 / Rev.9
BPP-15F	DISPOSABLE BIOPSY PUNCH WITH PLUNGER SYSTEM 1.5mm	KH-M-TF-05-R 2020-10-21 / Rev.9
BPP-20F	DISPOSABLE BIOPSY PUNCH WITH PLUNGER SYSTEM 2.0mm	KH-M-TF-05-R 2020-10-21 / Rev.9
BPP-30F	DISPOSABLE BIOPSY PUNCH WITH PLUNGER SYSTEM 3.0mm	KH-M-TF-05-R 2020-10-21 / Rev.9
BPP-40F	DISPOSABLE BIOPSY PUNCH WITH PLUNGER SYSTEM 4.0mm	KH-M-TF-05-R 2020-10-21 / Rev.9
LCH-PUK-10	DISPOSABLE BIOPSY PUNCH 1.0mm	KH-M-TF-05-R 2020-10-21 / Rev.9
LCH-PUK-15	DISPOSABLE BIOPSY PUNCH 1.5mm	KH-M-TF-05-R 2020-10-21 / Rev.9
LCH-PUK-20	DISPOSABLE BIOPSY PUNCH 2.0mm	KH-M-TF-05-R 2020-10-21 / Rev.9
LCH-PUK-25	DISPOSABLE BIOPSY PUNCH 2.5mm	KH-M-TF-05-R 2020-10-21 / Rev.9
LCH-PUK-30	DISPOSABLE BIOPSY PUNCH 3.0mm	KH-M-TF-05-R 2020-10-21 / Rev.9
LCH-PUK-35	DISPOSABLE BIOPSY PUNCH 3.5mm	KH-M-TF-05-R 2020-10-21 / Rev.9
LCH-PUK-40	DISPOSABLE BIOPSY PUNCH 4.0mm	KH-M-TF-05-R 2020-10-21 / Rev.9
LCH-PUK-50	DISPOSABLE BIOPSY PUNCH 5.0mm	KH-M-TF-05-R 2020-10-21 / Rev.9
LCH-PUK-60	DISPOSABLE BIOPSY PUNCH 6.0mm	KH-M-TF-05-R 2020-10-21 / Rev.9
LCH-PUK-80	DISPOSABLE BIOPSY PUNCH 8.0mm	KH-M-TF-05-R 2020-10-21 / Rev.9
48101	DISPOSABLE BIOPSY PUNCH 1.0mm	KH-M-TF-05-R 2020-10-21 / Rev.9
48115	DISPOSABLE BIOPSY PUNCH 1.5mm	KH-M-TF-05-R 2020-10-21 / Rev.9
48201	DISPOSABLE BIOPSY PUNCH 2.0mm	KH-M-TF-05-R 2020-10-21 / Rev.9
48251	DISPOSABLE BIOPSY PUNCH 2.5mm	KH-M-TF-05-R 2020-10-21 / Rev.9
48301	DISPOSABLE BIOPSY PUNCH 3.0mm	KH-M-TF-05-R 2020-10-21 / Rev.9
48351	DISPOSABLE BIOPSY PUNCH 3.5mm	KH-M-TF-05-R 2020-10-21 / Rev.9
48401	DISPOSABLE BIOPSY PUNCH 4.0mm	KH-M-TF-05-R 2020-10-21 / Rev.9

Catalogue No. (REF No.)	Description	Technical Documentation Issue Date/ Rev.
48501	DISPOSABLE BIOPSY PUNCH 5.0mm	KH-M-TF-05-R 2020-10-21 / Rev.9
48601	DISPOSABLE BIOPSY PUNCH 6.0mm	KH-M-TF-05-R 2020-10-21 / Rev.9
48801	DISPOSABLE BIOPSY PUNCH 8.0mm	KH-M-TF-05-R 2020-10-21 / Rev.9
49101	DISPOSABLE BIOPSY PUNCH WITH PLUNGER SYSTEM 1.0mm	KH-M-TF-05-R 2020-10-21 / Rev.9
49115	DISPOSABLE BIOPSY PUNCH WITH PLUNGER SYSTEM 1.5mm	KH-M-TF-05-R 2020-10-21 / Rev.9
49201	DISPOSABLE BIOPSY PUNCH WITH PLUNGER SYSTEM 2.0mm	KH-M-TF-05-R 2020-10-21 / Rev.9
49301	DISPOSABLE BIOPSY PUNCH WITH PLUNGER SYSTEM 3.0mm	KH-M-TF-05-R 2020-10-21 / Rev.9
49401	DISPOSABLE BIOPSY PUNCH WITH PLUNGER SYSTEM 4.0mm	KH-M-TF-05-R 2020-10-21 / Rev.9
Product Name : Dermal Curette		
MK402	DISPOSABLE DERMAL CURETTE 2mm	KH-M-TF-04-R 2020-10-21 / Rev.15
MK403	DISPOSABLE DERMAL CURETTE 3mm	KH-M-TF-04-R 2020-10-21 / Rev.15
MK404	DISPOSABLE DERMAL CURETTE 4mm	KH-M-TF-04-R 2020-10-21 / Rev.15
MK405	DISPOSABLE DERMAL CURETTE 5mm	KH-M-TF-04-R 2020-10-21 / Rev.15
MK407	DISPOSABLE DERMAL CURETTE 7mm	KH-M-TF-04-R 2020-10-21 / Rev.15
LCH-CUK-20	DISPOSABLE DERMAL CURETTE 2mm	KH-M-TF-04-R 2020-10-21 / Rev.15
LCH-CUK-30	DISPOSABLE DERMAL CURETTE 3mm	KH-M-TF-04-R 2020-10-21 / Rev.15
LCH-CUK-40	DISPOSABLE DERMAL CURETTE 4mm	KH-M-TF-04-R 2020-10-21 / Rev.15
LCH-CUK-50	DISPOSABLE DERMAL CURETTE 5mm	KH-M-TF-04-R 2020-10-21 / Rev.15
LCH-CUK-70	DISPOSABLE DERMAL CURETTE 7mm	KH-M-TF-04-R 2020-10-21 / Rev.15
50102	DISPOSABLE DERMAL CURETTE 2mm	KH-M-TF-04-R 2020-10-21 / Rev.15
50103	DISPOSABLE DERMAL CURETTE 3mm	KH-M-TF-04-R 2020-10-21 / Rev.15
50104	DISPOSABLE DERMAL CURETTE 4mm	KH-M-TF-04-R 2020-10-21 / Rev.15
50105	DISPOSABLE DERMAL CURETTE 5mm	KH-M-TF-04-R 2020-10-21 / Rev.15
50107	DISPOSABLE DERMAL CURETTE 7mm	KH-M-TF-04-R 2020-10-21 / Rev.15