EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60148506 0001

Report No.: 12022666 014

Manufacturer:
Kai Industries Co., Ltd.
1110 Oyana, Seki City
Gifu
501-3992 Japan

Products:
Surgical Blades, Scalpels, Biopsy Punches, Micro Surgical Scalpels and Dental Manual Instruments

Replaces Approval, Registration No.: HD 60135210 0001

Expiry Date: 2023-12-19

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-08-18

Date: 2020-08-18

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Takashi Matsuda

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60135210 0001
Report No.: 12022666 012

Manufacturer: Kai Industries Co., Ltd.
1110 Oyana, Seki City
Gifu 501-3992
Japan

Manufacturing site:
Kai Industries Co.,Ltd.
1110 Oyana, Seki City, Gifu 501-3992, Japan

Design and Development site:
Kai R&D Center Co., Ltd.
1110 Oyana, Seki City, Gifu 501-3992, Japan

Sterilization Method: Gamma Irradiation
Products, all for single use:
- Surgical Blades
- Scalpels
- Biopsy Punches
- Micro Surgical Scalpels
- Dental Manual Instruments

Sterilization Method: Ethylene Oxide Sterilization
Products, all for single use:
- Scalpels
- Biopsy Punches
- Micro Surgical Scalpels

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Notified Body

Date: 2018-12-14

M.Sc. M. Aihara

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Business Stream Products
Certification Department

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Kai Industries Co., Ltd.
1110 Oyana, Seki City, Gifu
501-3992 Japan

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date December 11, 2023

Notified Body Confirmation Letter
Reference. : KAI_CL607_2023-12-11

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Kai Industries Co., Ltd
1110 Oyana, Seki City, Gifu
501-3992 Japan
SRN Number: JP-MF-000016663

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by March 20, 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental

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Thomas Weigand, Spokesman

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Supervisory Board

Dr.-Ing. Michael Fübi

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fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body

Ning Chang
Ning N. C. Chang
Certification body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
MICROSURGERY KNIFE 456014692AA014H	Class IIa	Micro Surgical Scalpels	Certificate # HD 60148506 0001 NB # 0197
MICROSURGERY KNIFE 456214374AA014L	Class IIa	Micro Surgical Scalpels	Certificate # HD 60148506 0001 NB # 0197
SAFETY KNIFE 456014692AD014Y	Class IIa	Micro Surgical Scalpels	Certificate # HD 60148506 0001 NB # 0197
BIOPSY PUNCH 456014692AB014N	Class IIa	Biopsy Punches	Certificate # HD 60148506 0001 NB # 0197
DERMAL CURETTE 456014692AC014T	Class IIa	Biopsy Punches	Certificate # HD 60148506 0001 NB # 0197

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023-12-11	KAI_CL607_2023-12-11	Initial issue