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.

TÜVRheinland®

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