

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

Registration No.: HD 60090920 0001

Report No.: 12022666 001

Manufacturer: Kai Industries Co., Ltd.
1110 Oyana, Seki City
GIFU 501-3992
JAPAN

Products: Surgical Blades, Scalpels, Biopsy Punches and
Micro Surgical Scalpels
(see attachment for products and sites included)

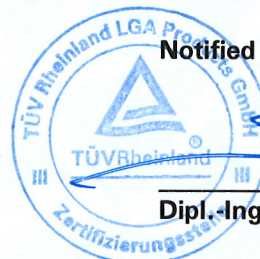
Replaces Approval, Registration No.: HD 60024932 0001

Expiry Date: 2018-12-19

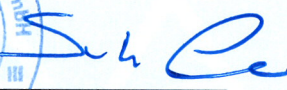
The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, 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: 2014-01-07

Date: 2014-01-07



Notified Body


Dipl.-Ing. S. Pane

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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60090920 0001
Report No.: 12022666 001

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:

- Surgical Blades
- Scalpels
- Biopsy Punches
- Micro Surgical Scalpels


Sterilization Method: Ethylene Oxide Sterilization
Products:

- Scalpels
- Biopsy Punches
- Micro Surgical Scalpels

Date: 2014-01-07



Notified Body


Dipl.-Ing. S. Pane