

APPROVAL
EC Directive 93/42/EEC Annex II, Article 3
Full Quality Assurance System
Medical Devices

Registration No.: HD 60024932 0001

Report No.: 12018101 001

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

Scope: Design and Development, Manufacture of Surgical Blades,
Scalpels, Biopsy Punches and Micro Surgical Scalpels

Production facility: see attachment

Products: see attachment

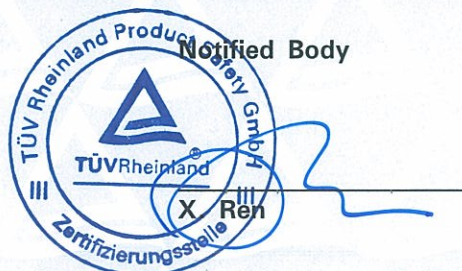
Sterilization Method: see attachment

Replaces Approval, Registration No.: HD 60007301 0001

Date of Expiry: 08.01.2014

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Cologne, 15.06.2009



TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. **0197** to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with.



TÜV Rheinland
Product Safety GmbH
Am Grauen Stein, D-51105 Köln

Doc. 1/1, Rev.0

Attachment to
Registration No.: HD 60024932 0001
Report No.: 12018101 001

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

Scope: Production facility:
Kai Industries Co., Ltd.
1110, Oyana, Seki City, Gifu Pref., Japan

Products:
- Surgical Blades
- Scalpels
- Biopsy Punches
- Micro Surgical Scalpels

Sterilization Method: Gamma Irradiation

Products:
- Scalpels
- Biopsy Punches
- Micro Surgical Scalpels

Sterilization Method: Ethylene Oxide Sterilization

Cologne, 15.06.2009

