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.

Notified Body

TÜV Rheinland Product Safety GmbH Zertifizierungsstelle TÜVRheinland X. Ren

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. CE

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Doc. 1/1, Rev.0

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

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

Certification Body

TÜV Rheinland Product Safety GmbH TÜVRheinland® Zertifizierungsstelle

Cologne, 15.06.2009