

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

has established and applies a quality management system for medical devices
for the following scope:

**Design and Development, Manufacture and Distribution of
Surgical Blades, Scalpels, Biopsy Punches, Dermal Curettes,
Micro Surgical Scalpels, Perforators for Dental Use,
Microtome Blades and Prep Razors**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016


are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-08-18
Certificate Registration No.: SX 60148507 0001
An audit was performed. Report No.: 12022666 014
This Certificate is valid until: 2021-11-30

Certification Body



Date 2020-08-18


Takashi Matsuda

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60134487 0001
Report No.: 12022666 010

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

Scope: Design and Development, Manufacture and Distribution of
Surgical Blades, Scalpels, Biopsy Punches, Dermal Curettes,
Micro Surgical Scalpels, Perforators for Dental Use,
Microtome Blades and Prep Razors

Certification Body



Date: 2018-11-30


M.Sc. M. Aihara

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

**Attachment to
Certificate**

Registration No.: SX 60134487 0001
Report No.: 12022666 010

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

Scope:

Sites included:

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

Scope:

Manufacture and Distribution of Surgical Blades, Scalpels,
Biopsy Punches, Dermal Curettes, Micro Surgical Scalpels,
Perforators for Dental Use, Microtome Blades and Prep Razors



Date: 2018-11-30

M. Aihara
M.Sc. M. Aihara

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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Certificate**

Registration No.: SX 60134487 0001
Report No.: 12022666 010

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

Scope:

Sites included:

Kai R&D Center Co., Ltd.
1110 Oyana, Seki City, Gifu, 501-3992 Japan

Scope:

Design and Development of Surgical Blades, Scalpels,
Biopsy Punches, Dermal Curettes, Micro Surgical Scalpels,
Perforators for Dental Use, Microtome Blades and Prep Razors

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Date: 2018-11-30

M. Aihara
M.Sc. M. Aihara