

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 2066395-1

Certificate Holder: Kai Industries Co., Ltd.
1110 Oyana,
Seki-shi, 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

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 150297273-301

Effective date: 2024-12-01

Expiry date: 2027-11-30

Issue date: 2024-11-14

Replaces certificate SX 2066395-1 issued 2021-11-26

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This certificate can be validated on <https://www.certipedia.com>