Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2066395-1

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

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.: 150245830-301
Effective date: 2021-12-01
Expiry date: 2024-11-30
Issue date: 2021-11-26

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierstelle

Dipl.-Ing. S. Pane
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Declaration of Conformity

Manufacturer: ERMA INC.
Address: 3-4-8 Kiuri Yoshikawa-shi, Saitama, 342-0045 Japan
SRN: JP-MF-0000-28225

European Representative: Umedwings Netherlands B.V.
Address: Treubstraat 1,2288EG,Rijswijk,The Netherlands
SRN: NL-AR-000000444

Product Name: Disposable Microtome Knife Patho Cutter

Model:

Ref No.	Product name
08-635-0	Patho Cutter - I 35°
08-635-1	Patho Cutter - II 35°
08-636-0	Patho Cutter -R 35°
08-637-0	Patho Cutter - R 22°
08-640-0	Pahto Cutter - HP
08-640-1	Patho Cutter - HP-R

Classification: Class A

Conformity Assessment Route:
Annex VIII of IVDR (EU) 2017/746.
We(Manufacturer) herewith declare that the above mentioned products and its accessories meet the following Regulation and standards. All supporting documentation is retained under the premises of the manufacturer.
We（Manufacturer）are exclusively responsible for the DOC.

General Applicable Directive:
Medical Device Directive: REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

Standards Applied:

EN ISO 13485: 2016	IVDR 2017/746	ISO 15223-1:2016
MEDDEV 2.12-1 Rev.8	ISO 14971:2019	ISO/TR 24971:2020

Erma Inc.

Name : Hiroshi Shimosaka
Position:President

Place: ,Tokyo, Japan
Date of Issue: December 21, 2022

CE