

Certificate

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.

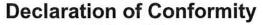
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Dipl.-Ing. S. Pane TÜV Rheinland LGA Products GmbH Tillystraße 2 · 90431 Nürnberg · Germany



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

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