

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	Patho 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





Certificate JP06/040143

The management system of

ERMA INC.

3-4-8 Kiuri, Yoshikawa-shi, Saitama-ken, 342-0045 Japan

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016



For the following activities

1. Manufacture and service of blood cell counters, spectrophotometric analyzers for IVD use and bilirubin analyzers
2. Distribution of in-vitro diagnostic products for hemoglobin measurement

This certificate is valid from 16 November 2021 until 16 November 2024 and remains valid subject to satisfactory surveillance audits. Recertification audit due a minimum of 60 days before the expiration date Issue 10. Certified since 16 November 2006

Authorised by



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ERMA Disposable Microtome Blades

PATHO CUTTER

ERMA Patho Cutter has been used by many customers in the world since 1995. Patho Cutter has been continuously developed and improved based on market trends and customers' opinions.

Durability was increased by the unique technology "PINK", Plasma Ion New Process by Kai, as hardness of the blade edge was improved by about 70%.

PINK technology, prioritizing both sharpness and durability, has been applied to blade edges of [Patho Cutter R Series](#), and these products have been received good reputation. A new product, Patho Cutter HP-R, has been just launched.

Six kinds of Patho Cutter are currently available to meet wide ranges of needs.

PATHO CUTTER-HP-R

35°

High Profile



New

Improved durability thanks to PINK technology. Suitable for slicing hard tissue and frozen samples.

PATHO CUTTER-R

35°

Low Profile



Especially recommended for rotary microtomes.

PATHO CUTTER-R

22°

Low Profile



Good use for extremely thin sections and Biopsies.

ERMA Disposable Microtome Blades

PATHO CUTTER

PATHO CUTTER-II 35°



Low Profile

Good for cryostat and rotary microtomes as well as sledge microtomes.

PATHO CUTTER-I 35°



Low Profile

Routine applications with consistent edge sharpness.

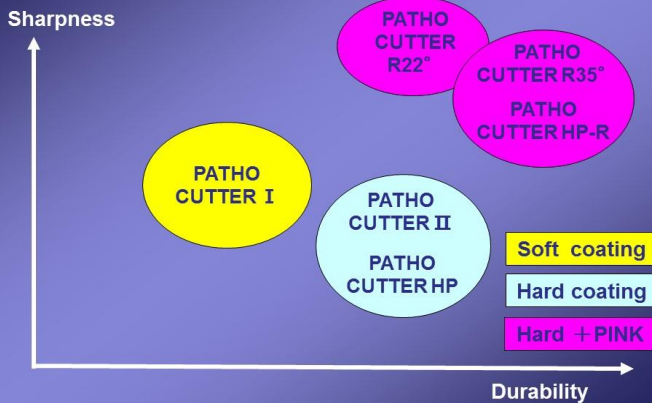
PATHO CUTTER-HP 35°



High Profile

Suitable for slicing hard tissue and frozen samples.

PATHO CUTTER Segmentation



Production process – PINK New Technology

PINK - Plasma Ion New process by KAI

Ultra Rigid Blade Technology

Innovative "PINK" special blade-hardening technology has improved durability.



TYPE	CONTENT	MATERIAL	DIMENSIONS	CAT. NO.
PATHO CUTTER-R 35°	50 blades	SPECIAL STAINLESS STEEL	0.25X8X80mm	08-636-0
PATHO CUTTER-R 22°	50 blades	SPECIAL STAINLESS STEEL	0.25X8X80mm	08-637-0
PATHO CUTTER-II 35°	50 blades	SPECIAL STAINLESS STEEL	0.25X8X80mm	08-635-1
PATHO CUTTER-I 35°	50 blades	SPECIAL STAINLESS STEEL	0.25X8X80mm	08-635-0
PATHO CUTTER-HP 35°	50 blades	SPECIAL STAINLESS STEEL	0.31X14X75mm	08-640-0
PATHO CUTTER-HP-R 35°	50 blades	SPECIAL STAINLESS STEEL	0.31X14X75mm	08-640-1

Subject to change without notice.



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