

# 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.

Report No.: 150245830-301  
Effective date: 2021-12-01  
Expiry date: 2024-11-30  
Issue date: 2021-11-26



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## DECLARATION OF CONFORMITY

Product Group:	Histological Instruments
General Product Group:	Microtome Blades
Product Name:	Microtome Blade
Product List:	See the attached CE Marked Product List
Product Lot. No.:	See the shipping records (This documentation is maintained by Kai Industries Co.,Ltd.)
IVD-Classification:	“Other” than those covered by Annex II
Manufacturer:	Kai Industries Co., Ltd. 1110 Oyana, Seki City, Gifu Pref., 501-3992, JAPAN
Applied Standards:	See the attached Document I
Authorized European Representative:	Kai Europe GmbH Kottendorfer Straße 5, 42697 Solingen, GERMANY
Responsible Person of European Representative:	Mr. Ryoichi Ogawa

The undersigned hereby declares that the *in vitro* diagnostic medical device as specified above conforms to the essential requirements listed in the Annex I of the European Directive 98/79/EC on *in vitro* diagnostic medical devices (IVDD). Conformity assessment procedure: according to 98/79/EC, Article 9 (1), Annex III.

This declaration of conformity is based on the fulfillment to the applicable harmonized standards.

Place and Date of issue:

Seki, October 18, 2018

  
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 Takeshi Mizutani  
 Senior Managing Director,  
 Kai Industries Co., Ltd.

## **Attached Document I : List of applied standards**

- **EN ISO 13485:2016**
- **EN ISO 13485:2016/AC:2016**  
Medical devices - Quality management systems - Requirements for regulatory purposes
- **EN ISO 14971:2012**  
Medical devices - Application of risk management to medical devices
- **EN 1041:2008+A1:2013**  
Information supplied by the manufacturer of medical devices
- **EN ISO 15223-1: 2016**  
Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied — Part 1:General requirements
- **EN 62366:2008**  
Medical devices. Application of usability engineering to medical devices

**CE Marked Product List - Microtome Blades**

Revision No. / Date : Rev.2 / 2019-07-01

General Product Group : Microtome Blades

Classification : Other IVDs

EDMA Code : 23 06 02

Legal Manufacturer : Kai Industries Co., Ltd.


Manufacturing Facility : Kai Industries Co., Ltd. Oyana factory

R&amp;D Facility : Kai Industries Co., Ltd. Oyana factory

European Representative : Kai Europe GmbH

Allocation of all Products into Device Subcategories According to NBOG BPG 2009-3 : MD0106

Declaration of Conformity: initial Issue Date / Latest Revision : 2003-07-18 / 2018-10-18 (Rev.16)

Signature: 

Approved by: Takeshi Mizutani, Senior Managing Director

A. Sterilization Method : None

Catalogue No. (REF No.)	Description
<b>Product Name: Microtome Blade</b>	
08-635-0	PATHO CUTTER - I 35°
08-635-1	PATHO CUTTER - II 35°
08-637-0	PATHO CUTTER - R 22°
08-636-0	PATHO CUTTER - R 35°
08-640-0	PATHO CUTTER - HP
08-640-1	PATHO CUTTER - HP-R

# 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

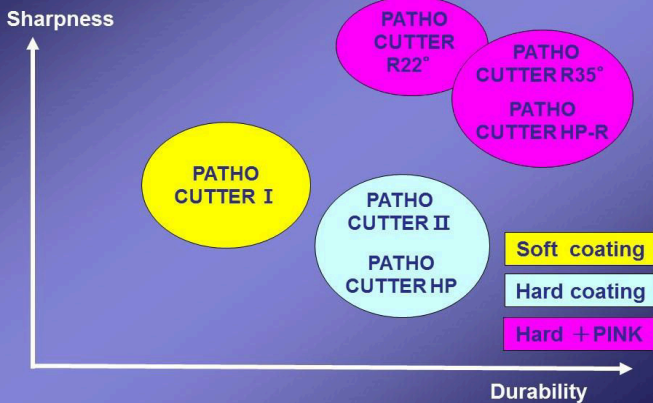
35°



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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