

## 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

