## **Declaration of Conformity**

 File:
 F\_Dec.\_IVD\_08

 Page:
 1 / 1

 Date:
 February-2023

Manufacturer:

FEATHER SAFETY RAZOR CO., LTD.

3-70, Ohyodo-Minami 3-chome, Kita-ku, Osaka, 531-0075 JAPAN

Facility:

FEATHER SAFETY RAZOR CO., LTD. MINO SITE

600-1, Matsumori, Mino-city, Gifu, 501-3753 JAPAN

**SRN Number** 

JP-MF-000018505

**Authorized Representative:** 

pfm medical ag

Wankelstr. 60, 50996 Köln, GERMANY

**SRN Number** 

DE-AR-000005340

We, FEATHER SAFETY RAZOR CO., LTD. located at 3-70, Ohyodo-Minami 3-chome, Kita-ku, Osaka, 531-0075 JAPAN herewith declare under our sole responsibility that the device(s) covered by this declaration is in conformity with Regulation (EU) 2017/746, General Safety and Performance requirements, and relevant Union legislation. Any alterations made without our consent shall render this declaration null and void.

Product category:

Pathological Instruments

Product group:

Microtome Blades

Classification:

Class A (acc. to Annex VIII of IVDR 2017/746)

Product name:

FEATHER MICROTOME BLADE

Model No. (Ref. No.):

S35 (02.075.00.000), S22 (02.075.00.001), A22 (02.075.00.002),

C35 (02.075.00.003), S35L (02.075.00.004), R35 (02.075.00.005), N35 (02.075.00.006), S35LL (02.075.00.009), FHP-01 (02.075.00.010),

A35 (02.075.00.011), N35HR (02.075.00.014), UNIVERSAL (02.074.00.000),

FHP-02 (02.075.00.016)

Basic UDI-DI

490247001MIBF5

Intended purpose of use:

The devices are intended for thin-sectioning of tissue that has been

processed for pathological examination.

EC-Directive:

Regulation (EU) 2017/746 (In-Vitro Diagnostic Medical Device Regulation)

Conformity Assessment Route:

Annex II and III, EU DECLARATION OF CONFORMITY

Common specifications

N/A

Place, Date:

GIFU JAPAN, February 1, 2023

Signature:

Satoli Prituishi

Satoshi Mitsuishi

Title:

**Executive Director**