

Declaration of Conformity

File:	F_Dec_IVD_08
Page:	1 / 1
Date:	July-2019

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

Authorized Representative : pfm medical ag
Wankelstr. 60, 50996 Köln, GERMANY

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 product(s) stated below are in conformity with the essential requirements and other relevant requirements of EC Directive 98/79/EC. Any alterations made without our consent shall render this declaration null and void.

Product category : Pathological Instruments

Product group : Microtome Blades

Classification : Other (acc. to Annex II of IVDD 98/79/EC)

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), High Profile (02.075.00.010), A35 (02.075.00.011), H35S (02.075.00.012), N35HR (02.075.00.014), SH35W (02.075.00.015), UNIVERSAL (02.074.00.000)

Intended purpose of use : Cutting instruments for microtomy

Start of CE marking : Lot No. 11010519

GMDN- Code : Microtome blade, Single use (42440)

EC-Directive : In-Vitro Diagnostic Medical Device Directive 98/79/EC

Conformity Assessment Route : Annex III, EC DECLARATION OF CONFORMITY

Standards applied : EN ISO 13485:2016/AC:2018, EN ISO 14971:2012, EN ISO 15223-1:2016

Place, Date : GIFU JAPAN, July 30, 2019

Signature :

Satoshi Mitsuishi

Title :