



FEATHER SAFETY RAZOR CO., LTD.

■ OVERSEAS TRADE DIVISION ■
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Declaration of Conformity

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Date: Dec.-2017

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
Wankelstraße 60, 50996 Cologne, Germany

We, FEATHER SAFETY RAZOR CO., LTD. located at 3-70, Ohyodo Minami 3-Chome, Kita-ku, Osaka, 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: Phathological Instruments

Product group: Microtome Blades

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

Product name: *Tissue-Tek Accu-Edge Microtome blades*

Model No. (Ref. No.): S35 - 02.076.00.000 (4689), S22 - 02.076.00.001 (4688), C35 - 02.076.00.003 (4810), R35 - 02.076.00.005 (4686), N35 - 02.076.00.006 (4690), A35 - 02.076.00.011 (4980), A22 - 02.076.00.013 (7089), N35HR - 02.076.00.014 (4691), High Profile - 02.077.00.000 (4685)

Intended purpose of use: Cutting instruments for microtomy

Start of CE marking : Lot No. 11011001

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 13485:2012/AC:2012, EN ISO 14971:2012, EN 980:2008

Place, Date: GIFU JAPAN, December 19, 2017

Signature:

Satoshi Mitunishi

Satoshi Mitsushi



Title:

Director