

Declaration of Conformity

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Date: September - 2020

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 93/42/EEC. Any alterations made without our consent shall render this declaration null and void.

Product category : Scalpels and Blades

Product group : Sterile surgical blades

Classification : Class IIa (acc. to Rule 6 Annex IX of MDD 93/42/EEC)

Product name : **FEATHER SURGICAL BLADE STAINLESS STEEL**

Model No. (Ref. No.) : No.10 (02.010.00.010), No.11 (02.010.00.011), No.12 (02.010.00.012),
No.12d (02.050.20.003), No.14 (02.051.40.003), No.15 (02.010.00.015),
No.15C (02.053.50.003), No.20 (02.010.00.020), No.21 (02.010.00.021),
No.22 (02.010.00.022), No.23 (02.010.00.023), No.24 (02.010.00.024),
No.25 (02.010.00.025), No.370 (02.010.00.370), No.390 (02.010.00.390),
No.390C (02.010.01.390), No.350 (02.010.00.350), No.391 (02.010.00.391)

Intended purpose of use : Cutting instruments for surgery

Start of CE marking : Lot No. 11019810

GMDN-Code : Scalpel blade, single-use (37445)

EC-Directive : Medical Device Directive 93/42/EEC


Conformity Assessment Route : Annex II excluding (4), Full quality assurance system

Standards applied : EN ISO 13485:2016/AC:2018, EN ISO 14971:2012,
EN ISO 10993-1:2009/AC2010, EN ISO 10993-5:2009, EN ISO 10993-10:2013,
EN ISO 10993-18:2009, EN ISO 11137-1:2015, EN ISO 11137-2:2015,
EN ISO 11737-1:2006/AC2009, EN ISO 11737-2:2009, EN ISO 11607-1:2009,
EN ISO 11607-2:2006, EN ISO 15223-1:2016, EN 1041:2008, EN 62366:2008,
EN ISO 14644-1:2015, JIS T 2107:2011, EN 62366:2008 AMENDMENT 1

Notified body : TÜV SÜD Product Service GmbH ID No.0123
Ridlerstraße 65, 80339 München, Germany

EC Certificate : No. G1 057582 0035 Rev.01

Place, Date : GIFU JAPAN, September 20, 2020

Signature :  Satoshi Mitsuishi

Title : Director