

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 : Disposable Scalpels

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

Product name : **FEATHER DISPOSABLE SCALPEL**
<SAFESHIELD SCALPEL>

Model No.(Ref. No.) : No.10 (02.001.40.010), No.11 (02.001.40.011), No.14 (02.001.40.014),
No.15 (02.001.40.015), No.15C (02.001.40.115), No.20 (02.001.40.020),
No.21 (02.001.40.021), No.22 (02.001.40.022), No.23 (02.001.40.023),
No.24 (02.001.40.024), No.25 (02.001.40.025)

Intended purpose of use : Cutting instruments for surgery

Start of CE marking : Lot No. 11015330

GMDN-Code : Scalpel, single use (47569)

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 29, 2020

Signature :  Satoshi Mitsuishi

Title : Director