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 DISSECTING BLADE***
Model No. (Ref. No.) :	**No.61 (02.056.00.001), No.62 (02.056.00.002)**
Intended purpose of use :	**Cutting instruments for surgery**
Start of CE marking :	**Lot No. 10129190**
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 29, 2020**
Signature :	Satoshi Mitsuishi **Satoshi Mitsuishi**
Title :	**Director**

TRADUZIONE

Dichiarazione di Conformità

Produttore	**FEATHER SAFETY RAZOR CO., LTD.** **3-70 Ohyodo Minami 3-chome, Kita-ku, Osaka, 531-0075 GIAPPONE**
Sede produttiva	**FEATHER SAFETY RAZOR CO., LTD., SEDE DI MINO** **600-1, Matsumori, Mino-city, Gifu, 501-3753 GIAPPONE**
Mandatario comunità europea	**pfm Produkte fur die Medizin AG** **Wankelstrasse 60, D-50996 Colonia, Germania**

Noi FEATHER SAFETY RAZOR CO., LTD. con sede a 3-70, Ohyodo-Minami 3-chome, Kita-ku, Osaka, 531-0075 GIAPPONE, con la presente dichiariamo sotto la nostra responsabilità che i prodotti elencati di seguito sono conformi ai requisiti essenziali e agli altri requisiti rilevanti della Direttiva Europea 93/42/CEE. Qualsiasi variazione apportata senza la nostra autorizzazione renderà la presente dichiarazione nulla e non più valida.

Categoria di prodotti:	**Bisturi e lame**
Gruppo di prodotti:	**Lame chirurgiche sterili**
Classificazione:	**Classe IIa (in conformità al punto 6 dell'Allegato IX della Direttiva dei Dispositivi Medici 93/42/CEE)**
Nome del prodotto:	**LAME PER DISSEZIONE FEATHER**
N° codici:	**N° 61 (02.056.00.001), N° 62 (02.056.00.002)**
Utilizzo previsto:	**Strumenti di taglio per chirurgia**
Inizio marcatura CE:	**Lotto n° 10129190**
Codice GMDN:	**Lame da bisturi monouso (37445)**
Direttiva CE:	**Direttiva 93/42/CEE Dispositivi Medici**
Metodo di valutazione di conformità:	**Allegato II escluso (4), Sistema completo di garanzia di qualità**
Standard applicati:	**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 EMENDAMENTO 1**
Ente notificato:	**TUV SUD Product Service GmbH ID No. 0123** **Ridlerstrasse 65, 80339 Monaco, Germania**
Certificato CE:	**No. G1 057582 0035 Rev. 01**
Luogo, data:	**GIFU, GIAPPONE, 29 settembre 2020**
Firma:	**Satoshi Mitsuishi**
Titolo:	**Presidente**

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 057582 0035 Rev. 01

Manufacturer:

FEATHER SAFETY RAZOR CO., LTD.
3-70, Ohyodo-Minami 3-chome, Kita-ku
Osaka
531-0075 JAPAN

Product Category(ies):

Scalpels and Blades
Disposable Dermatomes and Blades
Blood Lancets
Biopsy Punch

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 057582 0035 Rev. 01

Report No.: JN1530650

Valid from: 2020-08-28
Valid until: 2024-05-26

Date, 2020-08-28

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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