

# EC CERTIFICATE

## Full Quality Assurance System

Certificate No.:  
239655-2017-CE-IND-NA-PS Rev. 2.0

Project No.:  
PRJC-496563-2014-MSL-IND\_MDD

Valid Until:  
27-May-2024

This is to certify that the quality system of:

### SMB Corporation of India

13, 33 – 36, Prem Industrial Estate, Jogeshwari (E), Mumbai – 400 060, India

For design, production and final product inspection/testing of:  
**STERILE IUD THREAD RETRIEVER**

Has been assessed with respect to:

**THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN  
ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE  
93/42/EEC ON MEDICAL DEVICES, AS AMENDED**

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:  
**Høvik, 23 February 2021**

For:  
**DNV GL PRESAFE AS**  
**Notified Body No.: 2460**

**Tone Elise Kolpus**

The certificate is digitally verified by blockchain technology. For more info, see [www.dnvgl.com/assurance/certificates-in-the-blockchain.html](http://www.dnvgl.com/assurance/certificates-in-the-blockchain.html)



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## Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:s

Revision	Description	Issue Date
0.0	Supersedes DNVGL (NB0434) certificate no 180390-2015-CE-IND-NA following transfer of notified body functions to DNV GL Nemko Presafe AS (NB2460)	2017-06-01
1.0	Site Addition	2019-11-28
<b>2.0</b>	<b>Recertification</b>	2021-02-23

Products covered by this Certificate:

Product Description	Product Name	Class
Sterile IUD Thread retriever	IUD Thread retriever	Is

The complete list of devices is filed with the Notified Body

## Sites covered by this certificate

Site Name	Address
SMB Corporation of India	13, 33 – 36, Prem Industrial Estate, Jogeshwari (E), Mumbai – 400 060, India
SMB Corporation of India	Plot No. 156, GIDC, Umbergaon, Dist : Valsad, 396170, Gujarat, India

## EU Representative

Obelis s.a, Boulevard General Wahis 53, 1030 Brussels, Belgium

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## Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

## Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate