DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
239347-2017-CE-IND-NA-PS Rev. 4.0	PRJC-496563-2014-MSL-IND	27 February 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 INTRAUTERINE CONTRACEPTIVE DEVICES

Has been assessed with respect to:
THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II 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, 26 November 2019

NORWEGIAN ACCREDITATION

PROD 021

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Mariann Jeremiassen

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

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:

Revision	Description	Issue Date
0.0	Supersedes DNVGL (NB0434) certificate no 46275-2009-CE-IND-NA following transfer of notified body functions to DNV GL Nemko Presafe AS (NB2460)	2017-06-01
1.0	Addition of brand name (Rosa- U, Rosa – S, Rosa – V, Rosa – T, Rosa – Load, Rosa – Plus)	2018-01-17
2.0	Editorial corrections	2018-03-21
3.0	Recertification	2019-02-27
4.0	**Site Addition (in bold)**	**2019-11-26**

Products covered by this Certificate:

Product Description	Product Name	Class
Sterile Intrauterine Contraceptive Device with Copper	Copper T 380A • Rosa-T Model T Cu 380A	III*
Sterile Intrauterine Contraceptive Device with Copper	Copper T 380A with safe load • Rosa-load Model T Cu 380A with safe load	III*
Sterile Intrauterine Contraceptive Device with Copper	T Cu 380 Plus models: Mini, Normal & Maxi • UT380® Short and Standard • Rosa- plus Model T Cu 380 Plus Models : Mini, Normal & Maxi	III*
Sterile Intrauterine Contraceptive Device with Copper	Cu 375 Standard • Gynelle® 375 • Rosa-U Model Cu 375	III*
Sterile Intrauterine Contraceptive Device with Copper	Cu 375 Sleek • Rosa-S Model Cu 375 Sleek	III*
Sterile Intrauterine Contraceptive Device with Copper and Silver	TCu 380Ag models: Mini, Normal & Maxi • NT380® Short and Standard • Rosa- V Model TCu 380Ag Models : Mini, Normal & Maxi	III*
(All the above devices are with or without probe)		

* Design assessment is covered by a separate EC-Design Examination Certificate No.: 239653-2017-CE-IND-NA-PS Rev 2.0

Certificate No.:
239347-2017-CE-IND-NA-PS Rev. 4.0

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

Valid Until:
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Sites covered by this certificate

Site Name	Address
SMB Corporation of India	13, 33-36, Prem Industrial Estate, Subhash Road, 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

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