# EC Certificate
## Full Quality Assurance System

| Certificate No.: | Project number | Valid: |
|---|---|---|
| 239347-2017-CE-IND-NA-PS Rev 3.0 | 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 Article 11.3.a and 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, 27 February 2019**

NORWEGIAN ACCREDITATION
**PROD 021**
**Notified Body No.: 2460**

For:
**DNV GL PRESAFE AS**

**Mariann Jeremiassen**

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

# EC Certificate
## Full Quality Assurance System

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|---|---|---|
| 239347-2017-CE-IND-NA-PS Rev 3.0 | PRJC-496563-2014-MSL-IND | 27 February 2024 |

### 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** |

Products covered by this Certificate:

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

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

The complete list of devices is filed with the Notified Body

### Sites covered by this certificate

SMB Corporation of India, 13, 33 – 36, Prem Industrial Estate, Jogeshwari (E), Mumbai – 400 060, 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, through the contract partner, 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

# EC Design-Examination Certificate

| Certificate No.: | Project No.: | Valid: |
|---|---|---|
| 239653-2017-CE-IND-NA-PS Rev 2.0 | PRJC-496563-2014-MSL-IND | 27 February 2024 |

This is to certify that:

## Intrauterine Contraceptive Devices

Manufactured by:

## SMB Corporation of India

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

Has been assessed with respect to:

## The conformity assessment procedure described in Annex II 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, 27 February 2019**

NORWEGIAN ACCREDITATION
**PROD 021**
**Notified Body No.: 2460**

For:
**DNV GL PRESAFE AS**

**Mariann Jeremiassen**

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

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# EC Design-Examination Certificate

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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:

| 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** | **Recertification** | **2019-02-27** |

Products covered by this Certificate:

| **Type of medical device and identification no.:** | **Medical Device Class:** | **GMDN code:** |
|---|---|---|
| Intrauterine Contraceptive Devices:<br><br>Copper T 380A (TCu 380A)<br>• Rosa-T Model T Cu 380A<br><br>Copper T 380A with safe load<br>• Rosa-load Model T Cu 380A with safe load<br><br>TCu 380 Plus models Mini, Normal & Maxi<br>• UT380® Short and Standard<br>• Rosa- plus Model T Cu 380 Plus Mini<br>• Rosa- plus Model T Cu 380 Plus Normal<br>• Rosa- plus Model T Cu 380 Plus Maxi<br><br>Cu 375 Standard<br>• Gynelle® 375<br>• Rosa-U Model Cu 375<br><br>Cu 375 Sleek<br>• Rosa-S Model Cu 375 Sleek<br><br>TCu 380Ag models: Mini, Normal & Maxi<br>• NT380® Short and Standard<br>• Rosa- V Model TCu 380Ag Mini<br>• Rosa- V Model TCu 380Ag Normal<br>• Rosa- V Model TCu 380Ag Maxi<br><br>(All the above devices are with or without probe) | III | |

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**Short description of the Medical Device:**
The Copper-T 380A intra uterine contraceptive device is made of low density Polyethylene wound with copper wire. The "T" is equipped with high-density polyethylene tie thread and contains barium sulphate to render radio-opaque. In the model Copper T 380A with safe load, the "T" is also equipped with copper collars and is also with Safe load for easy loading of the IUD Copper T 380A

IUD Cu 375 (Models, Standard & Sleek) is made of low density polyethylene containing barium sulphate with two flexible arms with spurs, copper wire is wound around the stem giving a surface area of 375mm$^2$ with nylon monofilament attached to the stem.

TCu 380 Plus (models Mini, Normal & Maxi) intra uterine contraceptive device is made of made of Low Density Polyethylene wound with 0.40 mm diameter copper wire providing a surface area of 380 mm$^2$±23 mm$^2$. The 'T' is equipped with nylon thread (Suture) for easy removal and contains Barium Sulphate to render it radio-opaque. It is packed together with an insertion tube and Solid Rod in a Tyvek - Mylar film pouch or Mylar- Mylar film type 35726G pouch

The TCu 380Ag (Models, Mini, Normal, Maxi) intra uterine contraceptive device is made of made of Low Density Polyethylene wound with 0.40 mm diameter copper wire with silver core of 0.1 mm providing a surface area of 380 mm$^2$±23 mm$^2$. The 'T' is equipped with nylon thread (Suture) for easy removal and contains Barium Sulphate to render it radio-opaque. It is packed together with an insertion tube and Solid Rod in a Tyvek - Mylar film pouch or Mylar- Mylar film type 35726G pouch.

Sterilization method: Gamma radiation, ETO

The device is class III under rule 13 and a scientific opinion for the usefulness of the medicinal substance with ancillary effect has been sought as per Annex I, clause 7.4 and a positive opinion was received from the Medicine Evaluation Board, Netherlands was received on 25 June 2012 for IUDs containing silver and on 15 March 2013 for copper IUDs.

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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 inform Presafe of any intended change of the products detailed above and Presafe will assess the changes and decide if the certificate remains valid.

The following may render this Certificate invalid:

- Changes in the design of the products to which this Certificate refers.
- Changes in requirements of the scheme to which this Certificate refers.

## Conformity declaration and marking of product

This Certificate must be accompanied with a valid Certificate relating to quality of production.

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