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

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 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

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

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

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.

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

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

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:
27 February 2024

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

Notified Body Confirmation Letter Reference: C658589

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

SMB Corporation of India

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

SRN Number (if available): IN-MF-000023742

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

Place and date:
Høvik, 19.02.2024

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Menaka Singh
Management Representative

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function.
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device name: Copper T 380A (TCu 380A/CuT 380A) IUD **Basic UDI-DI:** 890602860SMBIUDTCU380AL6 **Brand Names:** Copper T 380A • Rosa-T Model T Cu 380A • EUROMEDIAL T380A Copper T 380A with safe load • Rosa-load Model T Cu 380A with safe load	**III**	Sterile Intrauterine Contraceptive Device with Copper Copper T380A, Copper T 380A with safe load (Name change only)	**MDD certificate Number :** 239347-2017-CE-IND-NA-Pas Rev 4.0 **MDD Certificate Appendix:** Rev 0, 1, 2 **Design certificate:** 239653-2017-CE-IND-NA-PS **2.0** **Design Certificate appendix:** Rev 0, 1 **NoBo Number:** 2460 **NoBo Name:** DNV Product Assurance AS
Device name: TCu380Plus IUD models: Mini, Normal & Maxi **Basic UDI-DI:** 890602860SMBIUD380PIus8R **Brand Names:** TCu380Plus models: Mini, Normal & Maxi • UT380® Short & standard • Rosa-Plus Model TCu380 Plus • Euromedial 380Cu, Models:	**III**	Sterile Intrauterine Contraceptive Device with Copper TCu380Plus models: Mini, Normal & Maxi (Name change only)	**MDD certificate Number :** 239347-2017-CE-IND-NA-Pas Rev 4.0 **MDD Certificate Appendix:** Rev 0, 1, 2 **Design certificate:** 239653-2017-CE-IND-NA-PS **2.0** **Design Certificate appendix:** Rev 0, 1

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Mini, Normal & Maxi			**NoBo Number:** 2460 **NoBo Name:** DNV Product Assurance AS
Device name: Cu 375 IUD Models :Standard and Sleek **Basic UDI-DI:** 890602860SMBIUDCU375GZ **Brand Names:** • Gynelle® 375 • Rosa-U Model Cu 375 • EUROMEDIAL 375 Cu Cu 375 Sleek • Rosa-S Model Cu 375 Sleek • EUROMEDIAL 375Cu Mini	**III**	Sterile Intrauterine Contraceptive Device with Copper Cu 375 Standard, Cu 375 Sleek (Name change only)	**MDD certificate Number :** 239347-2017-CE-IND-NA-Pas Rev 4.0 **MDD Certificate Appendix:** Rev 0, 1, 2 **Design certificate:** 239653-2017-CE-IND-NA-PS **2.0** **Design Certificate appendix:** Rev 0, 1 **NoBo Number:** 2460 **NoBo Name:** DNV Product Assurance AS
Device name: TCu 380Ag IUD Sizes : Mini, Normal & Maxi **Basic UDI-DI:** 890602860SMBIUDTCU380AgST **Brand Names:** TCu 380Ag models: Mini, Normal & Maxi • NT380® Short and Standard • Rosa- V Model TCu 380Ag • EUROMEDIAL 380Ag Models : Mini, Normal & Maxi	**III**	Sterile Intrauterine Contraceptive Device with Copper and Silver TCu380Ag Models: Mini, Normal & Maxi (Name change only)	**MDD certificate Number :** 239347-2017-CE-IND-NA-Pas Rev 4.0 **MDD Certificate Appendix:** Rev 0, 1, 2 **Design certificate:** 239653-2017-CE-IND-NA-PS **2.0** **Design Certificate appendix:** Rev 0, 1 **NoBo Number:** 2460 **NoBo Name:** DNV Product Assurance AS

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
NA	NA	NA	NA

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/12/15	C658589	Initial issue
2024/02/19	C658589	correction for a design certificate version

Lack of fulfilment of conditions

The following may render this letter of confirmation invalid:

- Lack of compliance to the requirements of Regulation (EU) 2023/607.
- Significant changes to design or intended purpose of the devices.
- Changes in the quality system affecting production.
- Periodical audits not held within the timeframe.