

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
Ministry of Health and Family welfare
(Medical Device and Diagnostic Division)

FREE SALE CERTIFICATE

FSC Number : **FSC/MD/2025/000146**

Dated : 05/03/2025

This is to certify that M/s. **SMB Corporation Of India** situated at address **13,34,35,36 Prem Industrial Estate, Subhash Road, Jogeshwari(E), Mumbai, Mumbai Suburban Maharashtra, 400060, 2228345637, 28246922, India** is holding Manufacturing License no. **MFG/MD/2020/000278** issued on **09-NOV-2020** Under this license, the said firm is permitted to manufacture the products for their manufacture and sale in domestic market as per Indian Law and for export as per law of importing country (ies):-

Name of the products with their product name and dimensions if any mentioned below :

S.NO	Medical Device Details
1	1. Generic Name : Copper T 380A (TCu 380A/CuT 380A)IUD 2. Brand Name : SMB 3. Notified Category : All implantable Medical Devices 4. Class of Medical Device : Class D 5. Shelf life : Up to 7 Years 6. Sterile/Non-Sterile: Sterilized 7. Intended Use : Intrauterine contraception in the women of Child bearing age 8. Material of Construction: T frame : LDPE Plus Barium sulphate, Tie Thread : High Density Polyethylene Plus TiO₂, Insertion Tube : High Density Polyethylene, Solid Rod : Polypropylene Plus TiO₂, Copper Components : Purity 99.99% as Cu 9. Dimension: Copper T 380A (TCu 380A/CuT 380A): vertical stem Length : 36 mm $\pm$ 5% and horizontal width 32 mm $\pm$ 5% 10. Model/Catalogue No./Name : Copper T 380A (TCu 380A/CuT 380A) IUD - WHO UNFPA Specification/ISO 7439/NDA 18680/MOH & FW New Delhi
2	1. Generic Name : Cu 375 IUD 2. Brand Name : SMB 3. Notified Category : All implantable Medical Devices 4. Class of Medical Device : Class D 5. Shelf life : Up to 5 Years 6. Sterile/Non-Sterile: Sterilized 7. Intended Use : Intrauterine contraception in the women of Child Bearing age 8. Material of Construction: T frame : LDPE Plus Barium sulphate, Tie Thread : Polyamide, Insertion Tube : High Density Polyethylene, Copper Components : Purity 99.99% as Cu 9. Dimension: Standard : Vertical stem Length : 36 mm $\pm$ 5% and width 18.7 mm $\pm$ 5%, Sleek : Vertical stem Length : 29.5 mm $\pm$ 5% and width 18.7 mm $\pm$ 5%, 10. Model/Catalogue No./Name : - , Cu 375 Standard - WHO UNFPA Specification/ISO 7439/MOH & FW New Delhi, Cu 375 Sleek - WHO UNFPA Specification/ISO 7439/MOH & FW New Delhi

3	1. Generic Name :Cu 250 IUD 2. Brand Name :SMB 3. Notified Category :All implantable Medical Devices 4. Class of Medical Device :Class D 5. Shelf life :Up to 5 years 6. Sterile/Non-Sterile:Sterilized 7. Intended Use :Intrauterine contraception in the women of Child Bearing Age 8. Material of Construction: T frame : LDPE Plus Barium sulphate,Tie Thread : Polyamide ,Insertion Tube : High Density Polyethylene, Copper Components : Purity 99.99% as Cu 9. Dimension: Standard :Vertical stem Length :36 mm $\pm$ 5% and width 18.7 mm $\pm$ 5%, Sleek :Vertical stem Length :29.5 mm $\pm$ 5% and width 18.7 mm $\pm$ 5%, 10. Model/Catalogue No./Name :Cu 250 Standard - ISO 7439/Inhouse ,Cu 250 Sleek - ISO 7439 / Inhouse
4	1. Generic Name :TCu 380Plus IUD 2. Brand Name :SMB 3. Notified Category :All implantable Medical Devices 4. Class of Medical Device :Class C 5. Shelf life :Up to 5 years 6. Sterile/Non-Sterile:Sterilized 7. Intended Use :Intrauterine Contraception in woman of child bearing age 8. Material of Construction: T frame : LDPE Plus Barium sulphate,Tie Thread : Polyamide ,Insertion Tube : High Density Polyethylene,Solid Rod : Polypropylene Plus TiO₂, Copper Components : Purity 99.99% as Cu 9. Dimension: Mini : Length 30.5 mm $\pm$ 5% and width 24 mm $\pm$ 5% ,Normal - Length 33 mm $\pm$ 5% and width 31 mm $\pm$ 5%, Maxi- Length 38mm $\pm$ 5% and width 36mm $\pm$ 5% 10. Model/Catalogue No./Name :TCu 380Plus Mini - ISO 7439/Inhouse ,TCu 380Plus Normal - ISO 7439/Inhouse ,TCu 380Plus Maxi - ISO 7439/Inhouse
5	1. Generic Name :TCu 375 Au IUD 2. Brand Name :SMB 3. Notified Category :All implantable Medical Devices 4. Class of Medical Device :Class D 5. Shelf life :Up to 5 years 6. Sterile/Non-Sterile:Sterilized 7. Intended Use :Intrauterine contraception in the woman of child bearing age 8. Material of Construction: T frame : LDPE Plus Barium sulphate,Tie Thread : Polyamide ,Insertion Tube : High Density Polyethylene,Solid Rod : Polypropylene Plus TiO₂, Copper/Au alloy wire (Cu 90% and Au 10%) 9. Dimension: : Mini : Length 30.5 mm $\pm$ 5% and width 24 mm $\pm$ 5% ,Normal - Length 33 mm $\pm$ 5% and width 31 mm $\pm$ 5%, Maxi- Length 38mm $\pm$ 5% and width 36mm $\pm$ 5% 10. Model/Catalogue No./Name :TCu 375 Au Mini - ISO 7439/Inhouse ,TCu 375 Au Normal - ISO 7439/Inhouse ,TCu 375Au Maxi - ISO 7439/Inhouse
6	1. Generic Name :TCu 380Ag IUD 2. Brand Name :SMB 3. Notified Category :All implantable Medical Devices 4. Class of Medical Device :Class C 5. Shelf life :Up to 5 years 6. Sterile/Non-Sterile:Sterilized 7. Intended Use :Intrauterine Contraception in the woman of child bearing age 8. Material of Construction: T frame : LDPE Plus Barium sulphate,Tie Thread : Polyamide ,Insertion Tube : High Density Polyethylene,Solid Rod : Polypropylene Plus TiO₂, Copper-Silver alloy wire 90%Copper +10% Silver) 9. Dimension: Mini : Length 30.5 mm $\pm$ 5% and width 24 mm $\pm$ 5% ,Normal - Length 33 mm $\pm$ 5% and width 31 mm $\pm$ 5%, Maxi- Length 38mm $\pm$ 5% and width 36mm $\pm$ 5% 10. Model/Catalogue No./Name :TCu 380Ag Mini - ISO 7439/Inhouse ,TCu 380Ag Normal - ISO 7439/Inhouse ,TCu 380Ag Maxi - ISO 7439/Inhouse
7	1. Generic Name :Cu 250 IUD with Probe 2. Brand Name :SMB 3. Notified Category :All implantable Medical Devices 4. Class of Medical Device :Class C 5. Shelf life :Up to 5 years 6. Sterile/Non-Sterile:Sterilized 7. Intended Use :Intrauterine contraception in the woman of child bearing age 8. Material of Construction: T frame : LDPE Plus Barium sulphate,Tie Thread : Polyamide ,Insertion Tube : High Density Polyethylene, Copper Components : Purity 99.99% as Cu 9. Dimension: Standard :Vertical stem Length :36 mm $\pm$ 5% and width 18.7 mm $\pm$ 5%, Sleek :Vertical stem Length :29.5 mm $\pm$ 5% and width 18.7 mm $\pm$ 5%, 10. Model/Catalogue No./Name :Cu 250 Sleek With probe - ISO 7439/Inhouse ,Cu 250 Standard With Probe - ISO 7439/Inhouse , -

8	1. Generic Name : Cu 375 IUD with Probe 2. Brand Name : SMB 3. Notified Category : All implantable Medical Devices 4. Class of Medical Device : Class D 5. Shelf life : Up to 5 years 6. Sterile/Non-Sterile: Sterilized 7. Intended Use : Intrauterine contraception in the woman of child bearing Age 8. Material of Construction: T frame : LDPE Plus Barium sulphate, Tie Thread : Polyamide , Insertion Tube : High Density Polyethylene, Copper Components : Purity 99.99% as Cu 9. Dimension: Standard : Vertical stem Length : 36 mm $\pm$ 5% and width 18.7 mm $\pm$ 5%, Sleek : Vertical stem Length : 29.5 mm $\pm$ 5% and width 18.7 mm $\pm$ 5%, 10. Model/Catalogue No./Name : Cu 375 Sleek with Probe - ISO 7439/Inhouse , Cu 375 Standard with Probe - ISO 7439/Inhouse
9	1. Generic Name : Copper T 380A(TCu 380A/CuT 380A)IUD with Probe 2. Brand Name : SMB 3. Notified Category : All implantable Medical Devices 4. Class of Medical Device : Class D 5. Shelf life : Up to 7 Years 6. Sterile/Non-Sterile: Sterilized 7. Intended Use : Intrauterine contraception in the woman of child bearing age 8. Material of Construction: T frame : LDPE Plus Barium sulphate, Tie Thread : High Density Polyethylene Plus TiO₂, Insertion Tube : High Density Polyethylene, Solid Rod : Polypropylene Plus TiO₂, Copper Components : Purity 99.99% as Cu 9. Dimension: Vertical stem Length : 36 mm $\pm$ 5% and Horizontal width 32 mm $\pm$ 5% 10. Model/Catalogue No./Name : Copper T380A(TCu380A/CuT 380A) IUD with Probe - WHO UNFPA Specification/ISO 7439/NDA 18680/MOH & FW New Delhi/Inhouse
10	1. Generic Name : Copper T 380A(TCu 380A/CuT 380A)IUD with Safe load and Probe 2. Brand Name : SMB 3. Notified Category : All implantable Medical Devices 4. Class of Medical Device : Class D 5. Shelf life : Up to 7 Years 6. Sterile/Non-Sterile: Sterilized 7. Intended Use : Intrauterine contraception in the woman of Child bearing age 8. Material of Construction: T frame : LDPE Plus Barium sulphate, Tie Thread : High Density Polyethylene Plus TiO₂, Insertion Tube : High Density Polyethylene, Solid Rod : Polypropylene Plus TiO₂, Copper Components : Purity 99.99% as Cu 9. Dimension: Vertical stem Length : 36 mm $\pm$ 5% and horizontal width 32 mm $\pm$ 5% 10. Model/Catalogue No./Name : Copper T380A(TCu380A/CuT 380A) IUD with Safe Load and Probe - WHO UNFPA Specification/ISO 7439/NDA 18680/MOH & FW New Delhi/Inhouse
11	1. Generic Name : TCu 380 Plus IUD with Probe 2. Brand Name : SMB 3. Notified Category : All implantable Medical Devices 4. Class of Medical Device : Class D 5. Shelf life : Up to 5 years 6. Sterile/Non-Sterile: Sterilized 7. Intended Use : Intrauterine contraception in the woman of child bearing age 8. Material of Construction: T frame : LDPE Plus Barium sulphate, Tie Thread : Polyamide , Insertion Tube : High Density Polyethylene, Solid Rod : Polypropylene Plus TiO₂, Copper Components : Purity 99.99% as Cu 9. Dimension: Mini : Length 30.5 mm $\pm$ 5% and width 24 mm $\pm$ 5% , Normal - Length 33 mm $\pm$ 5% and width 31 mm $\pm$ 5%, Maxi- Length 38mm $\pm$ 5% and width 36mm $\pm$ 5% 10. Model/Catalogue No./Name : TCu 380Plus Mini with Probe - ISO 7439/Inhouse , TCu 380Plus Normal with Probe - ISO 7439/Inhouse , TCu 380Plus Maxi with Probe - ISO 7439/Inhouse
12	1. Generic Name : Copper T 380A(TCu 380A/CuT 380A)- Post Delivery IUD 2. Brand Name : SMB 3. Notified Category : All implantable Medical Devices 4. Class of Medical Device : Class D 5. Shelf life : Up to 7 Years 6. Sterile/Non-Sterile: Sterilized 7. Intended Use : Intrauterine contraception in the woman of child bearing age 8. Material of Construction: T frame : LDPE Plus Barium sulphate, Tie Thread : High Density Polyethylene Plus TiO₂, Insertion Tube : High Density Polyethylene, Solid Rod : Polypropylene Plus TiO₂, Copper Components : Purity 99.99% as Cu 9. Dimension: Vertical stem Length : 36 mm $\pm$ 5% and horizontal width 32 mm $\pm$ 5% 10. Model/Catalogue No./Name : NIL

13	1. Generic Name :Tubal Ring 2. Brand Name :SMB 3. Notified Category :All implantable Medical Devices 4. Class of Medical Device :Class C 5. Shelf life :4 Years 6. Sterile/Non-Sterile:Sterilized 7. Intended Use :Contraception in woman 8. Material of Construction: Silicon Rubber 9. Dimension: ID. =1.0 +/- 0.1 mm, OD = 4.0 mm ± 0.3 mm,Thickness= 2.5 mm± 0.0.15 mm 10. Model/Catalogue No./Name :Tubal Ring/Fallopian Tube Ring - IS 13009
14	1. Generic Name :TCu 380Ag IUD with Probe 2. Brand Name :SMB 3. Notified Category :All implantable Medical Devices 4. Class of Medical Device :Class D 5. Shelf life :Up to 5 years 6. Sterile/Non-Sterile:Sterilized 7. Intended Use :Intrauterine Contraception in the woman of Child bearing age 8. Material of Construction: T frame : LDPE Plus Barium sulphate,Tie Thread : Polyamide „Insertion Tube : High Density Polyethylene,Solid Rod : Polypropylene Plus TiO₂, and Copper-Silver alloy wire(90%Copper +10% Silver) 9. Dimension: Mini : Length 30.5 mm ± 5% and width 24 mm ± 5% ,Normal - Length 33 mm ± 5% and width 31 mm ± 5%, Maxi- Length 38mm ± 5% and width 36mm ± 5% 10. Model/Catalogue No./Name :TCu 380 Ag Maxi with Probe - ISO 7439/Inhouse ,TCu 380 Ag Normal with Probe - ISO 7439/Inhouse ,TCu 380Ag Mini with Probe - ISO 7439/Inhouse



Competent Authority