

**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/2024/000416**

Dated : 10/07/2024

This is to certify that M/s. **SMB Corporation Of India ,SMB Medical Devices Pvt Ltd** situated at address **156 GIDC UMBERGAON ,Valsad Gujarat ,396170,02602560209, India** is holding Manufacturing License no. **MFG/MD/2020/000275** issued on **04-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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
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| 1    | <b>1. Generic Name :</b> Copper T 380A (TCu 380A/CuT 380A) IUD<br><b>2. Brand Name :</b> SMB<br><b>3. Notified Category :</b> Intra Uterine Devices (Cu-T)<br><b>4. Class of Medical Device :</b> Class D<br><b>5. Shelf life :</b> Up to 7 years<br><b>6. Sterile/Non-Sterile:</b> Sterilized<br><b>7. Intended Use :</b> Intrauterine contraception in the woman of Child Bearing Age<br><b>8. Material of Construction:</b> Plastic and Copper<br><b>9. Dimension:</b> Copper T 380A : 36 mm $\pm$ 5% and width 32 mm $\pm$ 5%<br><b>10. Model/Catalogue No./Name :</b> Copper T 380A (TCu 380A/CuT 380A) IUD - WHO UNFPA Specification/ISO 7439/NDA 18-680/MOH & FW New Delhi                                                                                                                                              |
| 2    | <b>1. Generic Name :</b> Cu 375 IUD<br><b>2. Brand Name :</b> SMB<br><b>3. Notified Category :</b> Intra Uterine Devices (Cu-T)<br><b>4. Class of Medical Device :</b> Class D<br><b>5. Shelf life :</b> 5 Years<br><b>6. Sterile/Non-Sterile:</b> Sterilized<br><b>7. Intended Use :</b> Intrauterine contraception in the woman of Child bearing age<br><b>8. Material of Construction:</b> Plastic and Copper<br><b>9. Dimension:</b> Standard :Vertical stem Length :36 mm $\pm$ 5% and width 18.7 mm $\pm$ 5%,<br>Sleek :Vertical stem Length :29.5 mm $\pm$ 5% and width 18.7 mm $\pm$ 5%,<br><b>10. Model/Catalogue No./Name :</b> Cu 375 IUD Sleek - WHO UNFPA Technical Specification /ISO 7439 /MOH & FW Specifications of Govt. Of India ,Cu 375 IUD Standard - WHO UNFPA Specification/ISO 7439/MOH & FW New Delhi |

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| 3 | <p>1. <b>Generic Name</b> :Cu 250 IUD</p> <p>2. <b>Brand Name</b> :SMB</p> <p>3. <b>Notified Category</b> :Intra Uterine Devices (Cu-T)</p> <p>4. <b>Class of Medical Device</b> :Class D</p> <p>5. <b>Shelf life</b> :5 Years</p> <p>6. <b>Sterile/Non-Sterile</b>:Sterilized</p> <p>7. <b>Intended Use</b> :Intrauterine contraception in the woman of Child Bearing age</p> <p>8. <b>Material of Construction</b>: Plastic and Copper</p> <p>9. <b>Dimension</b>: Standard :Vertical stem Length :36 mm <math>\pm</math> 5% and width 18.7 mm <math>\pm</math> 5%, Slek :Vertical stem Length :29.5 mm <math>\pm</math> 5% and width 18.7 mm <math>\pm</math> 5%,</p> <p>10. <b>Model/Catalogue No./Name</b> :Cu 250 IUD Standard - ISO 7439/Inhouse ,Cu 2650 IUD Slek - ISO 7439/Inhouse</p>                                                                                                       |
| 4 | <p>1. <b>Generic Name</b> :TCu 380Ag IUD</p> <p>2. <b>Brand Name</b> :SMB</p> <p>3. <b>Notified Category</b> :Intra Uterine Devices (Cu-T)</p> <p>4. <b>Class of Medical Device</b> :Class D</p> <p>5. <b>Shelf life</b> :5 Years</p> <p>6. <b>Sterile/Non-Sterile</b>:Sterilized</p> <p>7. <b>Intended Use</b> :Intrauterine Contraception in the woman of Child bearing age</p> <p>8. <b>Material of Construction</b>: Plastic and Copper-Silver alloy wire</p> <p>9. <b>Dimension</b>: Mini : Length 30.5 mm <math>\pm</math> 5% and width 24 mm <math>\pm</math> 5% ,Normal - Length 33 mm <math>\pm</math> 5% and width 31 mm <math>\pm</math> 5%, Maxi- Length 38mm <math>\pm</math> 5% and width 36mm <math>\pm</math> 5%</p> <p>10. <b>Model/Catalogue No./Name</b> :TCu 380Ag IUD Mini - Inhouse/ISO 7439 ,TCu 380Ag IUD Normal - Inhouse/ISO 7439 ,TCu 380Ag IUD Maxi - Inhouse/ISO 7439</p> |
| 5 | <p>1. <b>Generic Name</b> :Copper T 380A (TCu 380A/CuT380A) IUD with Safe Load and Probe</p> <p>2. <b>Brand Name</b> :SMB</p> <p>3. <b>Notified Category</b> :Intra Uterine Devices (Cu-T)</p> <p>4. <b>Class of Medical Device</b> :Class D</p> <p>5. <b>Shelf life</b> :Up to 7 years</p> <p>6. <b>Sterile/Non-Sterile</b>:Sterilized</p> <p>7. <b>Intended Use</b> :Intrauterine contraception in the woman of Child bearing age</p> <p>8. <b>Material of Construction</b>: Plastic and Copper</p> <p>9. <b>Dimension</b>: Copper T 380A : 36 mm <math>\pm</math> 5% and width 32 mm <math>\pm</math> 5%</p> <p>10. <b>Model/Catalogue No./Name</b> :Copper T 380A (TCu 380A/CuT380A) IUD With safe Load and Probe - WHO UNFPA Specification/ISO 7439/NDA 18-680/MOH &amp; FW New Delhi</p>                                                                                                         |
| 6 | <p>1. <b>Generic Name</b> :Tubal Rings</p> <p>2. <b>Brand Name</b> :SMB</p> <p>3. <b>Notified Category</b> :Tubal Rings</p> <p>4. <b>Class of Medical Device</b> :Class C</p> <p>5. <b>Shelf life</b> :4 Years</p> <p>6. <b>Sterile/Non-Sterile</b>:Sterilized</p> <p>7. <b>Intended Use</b> :Contraception in woman</p> <p>8. <b>Material of Construction</b>: Silicon Rubber</p> <p>9. <b>Dimension</b>: ID. =1.0 +/_ 0.1 mm, OD = 4.0 mm <math>\pm</math> 0.3 mm,Thickness= 2.5 mm<math>\pm</math> 0.0.15 mm</p> <p>10. <b>Model/Catalogue No./Name</b> :Tubal Ring/Fallopian Tube Ring - IS 13009</p>                                                                                                                                                                                                                                                                                              |

Competent Authority