



सत्यमेव जयते

FORM MD-10

[See sub-rule (1) rule 25]

Loan Licence to Manufacture for Sale or for Distribution of Class C or Class D medical device

Loan Licence Number: MFG/MD/2020/000275

1. M/s SMB Corporation Of India, 13,33-36 Prem Industrial Estate,Subhash Road,Jogeshwari(E),Mumbai Mumbai, --, Maharashtra (India) - 400060 Telephone No.: 2228345637 FAX: 2228215157 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s SMB Medical Devices Pvt Ltd, 156 GIDC UMBERGAON, Valsad, Gujarat (India) - 396170 Telephone No.: 02602560209 FAX: 022 28215157
2. Details of medical device(s) [Annexed]
3. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s): As per records maintain by the manufacturer
4. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	<p>Generic Name:Copper T 380A (TCu 380A/CuT 380A) IUD Model No.:Copper T 380A (TCu 380A/CuT 380A) IUD - WHO UNFPA Specification/ISO 7439/NDA 18-680/MOH & FW New Delhi Intended Use:Intrauterine contraception in the woman of Child Bearing Age Class of medical device:Class D Material of construction:Plastic and Copper Dimension(if any):Copper T 380A : 36 mm \pm 5% and width 32 mm \pm 5% Shelflife:Up to 7 years Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):SMB</p>
2	<p>Generic Name:Cu 375 IUD Model No.: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 Intended Use:Intrauterine contraception in the woman of Child bearing age Class of medical device:Class D Material of construction:Plastic and Copper Dimension(if any):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%, Shelflife:5 Years Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):SMB</p>

3	<p>Generic Name:Cu 250 IUD Model No.:Cu 250 IUD Standard - ISO 7439/Inhouse ,Cu 2650 IUD Sleek - ISO 7439/Inhouse Intended Use:Intrauterine contraception in the woman of Child Bearing age Class of medical device:Class D Material of construction:Plastic and Copper Dimension(if any):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%, Shelflife:5 Years Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):SMB</p>
4	<p>Generic Name:TCu 380Ag IUD Model No.:TCu 380Ag IUD Mini - Inhouse/ISO 7439 ,TCu 380Ag IUD Normal - Inhouse/ISO 7439 ,TCu 380Ag IUD Maxi - Inhouse/ISO 7439 Intended Use:Intrauterine Contraception in the woman of Child bearing age Class of medical device:Class D Material of construction:Plastic and Copper-Silver alloy wire Dimension(if any):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% Shelflife:5 Years Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):SMB</p>
5	<p>Generic Name:Copper T 380A (TCu 380A/CuT380A) IUD with Safe Load and Probe Model No.:Copper T 380A (TCu 380A/CuT380A) IUD With safe Load and Probe - WHO UNFPA Specification/ISO 7439/NDA 18-680/MOH & FW New Delhi Intended Use:Intrauterine contraception in the woman of Child bearing age Class of medical device:Class D Material of construction:Plastic and Copper Dimension(if any):Copper T 380A : 36 mm \pm 5% and width 32 mm \pm 5% Shelflife:Up to 7 years Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):SMB</p>
6	<p>Generic Name:Tubal Rings Model No.:Tubal Ring/Fallopian Tube Ring - IS 13009 Intended Use:Contraception in woman Class of medical device:Class C Material of construction:Silicon Rubber Dimension(if any):ID. =1.0 +/- 0.1 mm, OD = 4.0 mm \pm 0.3 mm,Thickness= 2.5 mm\pm 0.0.15 mm Shelflife:4 Years Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):SMB</p>

Place:

Date04-Nov-20

Central Licensing Authority