THE UNITED REPUBLIC OF TANZANIA
TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

TMDA
Tanzania Medicines & Medical Devices Authority

CERTIFICATE OF MEDICAL DEVICE REGISTRATION

(Made under Section 53(4) (iii) of the Tanzania Medicines and Medical Devices Act, Cap 219)

Registration number: **TAN 20 MDR 0197**

This is to certify that the Medical Device described below has been registered in Tanzania subject to conditions indicated:.

Trade name of the device:	**SMB TCU 380AG**
Common Name:	**INTRAUTERINE CONTRACEPTIVE DEVICE**
Class of the device:	**CLASS D**
GMDN Code and Term:	**46920 & INTRAUTERINE DEVICE, METAL-COVERED**
Commercial Presentation:	**1 COMPLETE PACK**
Name of Marketing Authorization Holder:	**SMB CORPORATION OF INDIA**
Name and address of the Manufacturer:	**SMB CORPORATION OF INDIA** **SMB CORPORATION OF INDIAPREM INDUSTRIAL ESTATESUBHASHI RD, JOGESHWARI EAST,MUMBAI - 400 060, INDI** **MUMBAI - 400 060** **MUMBAI INDIA**
Local Responsible Person:	**DKT INTERNATIONAL TANZANIA**
Issued on:	**March 06, 2020**
Expires on:	**March 05, 2025**

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A. M. FIMBO

ACTING DIRECTOR GENERAL

- The certificate must be returned to the Authority if canceled, invalidated or if registration of the medical device is withdrawn or when requested to do so by the Director General.
- The conditions for registration are outlined overleaf:

Conditions of Registration:

1. The medical device shall comply with all relevant provisions of the Tanzania Medicines and Medical Devices Act, Cap 219 and regulations made there under at all times.

2. The marketing authorization holder shall ensure that the medical device complies with specifications approved by the Authority at all times.

3. The marketing authorization holder shall ensure that the medical device complies with Tanzanian labeling requirements at all times.

4. The marketing authorization holder shall ensure that the manufacturing facilities where a registered medical device is produced comply at all times with applicable ISO Standards.

5. The marketing authorization holder and Local Responsible Person shall ensure that medical device within their control are stored and transported in accordance with the instructions and information provided by the manufacturer.

6. The marketing authorization holder shall ensure that application for renewal of registration is made 90 days before expiry of registration.

7. The resgistration of the medical device shall continue to be valid for 5 years provided that annual retention fee is paid annually before 31st of January each Year.

8. The marketing authorization holder is duty bound to conduct periodic post-marketing surveillance and safety studies of registered medical device and report the outcome of such studies to the Authority.

9. All changes with regard to a registered medical device should be notified to the Authority for approval prior to their implementation.

10. The Authority reserves the right to withdrawal this certificate when conditions 1 to 9 are contravened and when the risks of the medical device outweighs the benefits or it is in public interest to do so.

THE UNITED REPUBLIC OF TANZANIA
TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

TMDA
Tanzania Medicines & Medical Devices Authority

CERTIFICATE OF MEDICAL DEVICE REGISTRATION

(Made under Section 53(4) (iii) of the Tanzania Medicines and Medical Devices Act, Cap 219)

Registration number: **TAN 20 MDR 0187**

This is to certify that the Medical Device described below has been registered in Tanzania subject to conditions indicated:.

Trade name of the device:	**SMB CU 375**
Common Name:	**INTRAUTERINE CONTRACEPTIVE DEVICE**
Class of the device:	**CLASS D**
GMDN Code and Term:	**46920 & INTRAUTERINE DEVICE, METAL-COVERED**
Commercial Presentation:	**1 COMPLETE PACK**
Name of Marketing Authorization Holder:	**SMB CORPORATION OF INDIA**
Name and address of the Manufacturer:	**SMB CORPORATION OF INDIA** **SMB CORPORATION OF INDIAPREM INDUSTRIAL ESTATESUBHASHI RD, JOGESHWARI EAST,MUMBAI - 400 060, INDI** **MUMBAI - 400 060** **MUMBAI INDIA**
Local Responsible Person:	**DKT INTERNATIONAL TANZANIA**
Issued on:	**March 06, 2020**
Expires on:	**March 05, 2025**

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A. M. FIMBO

ACTING DIRECTOR GENERAL

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Conditions of Registration:

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3. The marketing authorization holder shall ensure that the medical device complies with Tanzanian labeling requirements at all times.

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5. The marketing authorization holder and Local Responsible Person shall ensure that medical device within their control are stored and transported in accordance with the instructions and information provided by the manufacturer.

6. The marketing authorization holder shall ensure that application for renewal of registration is made 90 days before expiry of registration.

7. The resgistration of the medical device shall continue to be valid for 5 years provided that annual retention fee is paid annually before 31st of January each Year.

8. The marketing authorization holder is duty bound to conduct periodic post-marketing surveillance and safety studies of registered medical device and report the outcome of such studies to the Authority.

9. All changes with regard to a registered medical device should be notified to the Authority for approval prior to their implementation.

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CERTIFICATE OF MEDICAL DEVICE REGISTRATION

(Made under Section 53(4) (iii) of the Tanzania Medicines and Medical Devices Act, Cap 219)

Registration number: **TAN 20 MDR 0201**

This is to certify that the Medical Device described below has been registered in Tanzania subject to conditions indicated:.

Trade name of the device:	**SMB COPPER T 380A**
Common Name:	**INTRAUTERINE CONTRACEPTIVE DEVICE**
Class of the device:	**CLASS D**
GMDN Code and Term:	**46920 & INTRAUTERINE DEVICE, METAL-COVERED**
Commercial Presentation:	**1 COMPLETE SET**
Name of Marketing Authorization Holder:	**SMB CORPORATION OF INDIA**
Name and address of the Manufacturer:	**SMB CORPORATION OF INDIA** **SMB CORPORATION OF INDIAPREM INDUSTRIAL ESTATESUBHASHI RD, JOGESHWARI EAST,MUMBAI - 400 060, INDI** **MUMBAI - 400 060** **MUMBAI INDIA**
Local Responsible Person:	**DKT INTERNATIONAL TANZANIA**
Issued on:	**March 06, 2020**
Expires on:	**March 05, 2025**

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ACTING DIRECTOR GENERAL

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Conditions of Registration:

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3. The marketing authorization holder shall ensure that the medical device complies with Tanzanian labeling requirements at all times.

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5. The marketing authorization holder and Local Responsible Person shall ensure that medical device within their control are stored and transported in accordance with the instructions and information provided by the manufacturer.

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