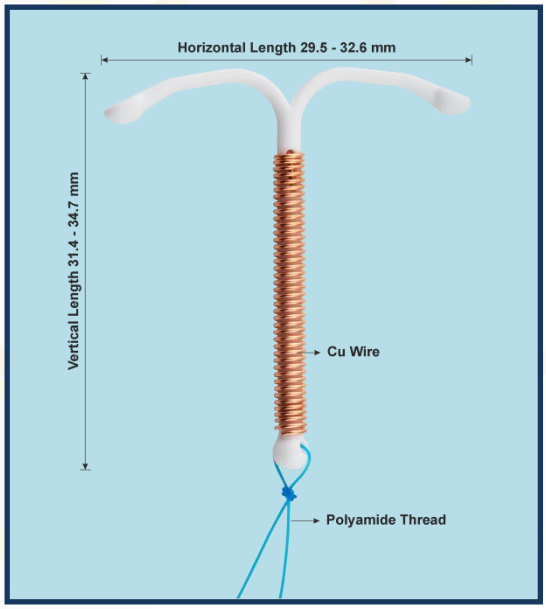
SMB CORPORATION OF INDIA
Prem Industrial Estate, Subhash Road,
Jogeshwari (E), Mumbai - 400 060

CE 2460

EC DECLARATION OF CONFORMITY

Manufacturer	:	SMB Corporation of India Unit I: 13, 33-36, Prem Industrial Estate, Subhash Road, Jogeshwari (E), Mumbai, India-400 060.
Manufacturer's SRN	:	IN-MF-000023742
Authorized Representative	:	Obelis S.A. Boulevard Général Wahis 53, 1030 Brussels, Belgium. +32(2)73 25 954 E -mail : regulatory@obelis.net
Authorized Representative's SRN	:	BE-AR-000000106
Device Name & Models	:	TCu 380Plus (SMB TCu380Plus Normal)
Photograph of Representative Device	:	
Basic UDI-DI	:	890602860SMBIUDTCU380Plus8R
Intended Purpose	:	The TCu380 Plus IUD is indicated for intrauterine contraception in women of childbearing age
EMDN Code and Description	:	U110201 INTRAUTERINE COILS
Batch No / LOT No.	:	PN0XXX-XXXX
Risk Classification	:	Class III
Classification Rule	:	Rule 13
Applicable Standards (Harmonized)	:	EN ISO 13485:2016/A11:2021, EN ISO 14971:2019/A11:2021, EN ISO 15223-1:2021, EN ISO 10993-12:2021, EN ISO 10993-23:2021, EN ISO 11137-1:2015/A2:2019, EN ISO 11737- 1:2018/A1:2021, EN ISO 11737-2:2020,

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Applicable Standards and Guidance	:	EN ISO 7439:2023, EN ISO 20417:2021, ISO/ TR 24971: 2020, EN ISO 11607-1:2020, EN ISO 11607-2:2020, MEDDEV 2.7.1., Rev 4, MDCG 2020-6, MDCG 2019-9, Rev.1, IEC 62366-1:2015/AMD1:2020, MDCG 2019-8, V2, MDCG 2021-11, ASTM D 3078-02:2021, ASTM F88/F88M-21, ASTM F2054/F2054M-13:2020, ASTM D4169-22, ASTM D 5276-19, ASTM D 5487- 16(2022), ASTM D999-08(2015), ASTM D4728-17, ASTM D 642-20, EN ISO 10993-1:2020, EN ISO 10993-3:2014, EN ISO 10993-5:2009, EN ISO 10993-6:2016, ISO 10993-10:2021, EN ISO 10993-11:2018, EN ISO 10993-15:2009, EN ISO 10993- 18:2020, EN ISO 11137-2:2020, ISO 14644-1:2015, ISO 14644-2:2015, ISO 14644-3:2019, ISO 14644-4:2001, EN 17141:2020, ISO/ TR 20416: 2020, MDCG 2020-7, MDCG 2020-8,
Route of Conformity Assessment:	:	Article 11.3a and Annex II (Module H1) of Council Directive 93/42/EEC on Medical device

We declare on our sole responsibility that the above products with CE mark are complying with the procedure set out in MDD in general and conformity assessment procedure described in Article 11.3a and Annex II (Module H1) of Council Directive 93/42/EEC on Medical device, as amended. The device is classified as Class III device as per rule 13. The products full fill the requirements of Directive and are in compliance with ISO 7439:2023 Standard as applicable.

Notified Body	:	DNV Product Assurance AS
Notified Body No.	:	2460
Date of First CE Marking:	:	2013
Applicable CE Certificate(s)	:	239347-2017-CE-IND-NA-PS.rev 4.0
Authorized Signatory	:	**For SMB Corporation of India**
Signature	:	
Name & Designation	:	Anupam Rai, Chief QA
Issue Date & Location	:	10.07.2024, Mumbai