



SMB Corporation of India
Prem Industrial Estate Subhash Road Jogeshwari(E).
Mumbai 400060



EC DECLARATION OF CONFORMITY

2460

2460

Device Description: Intrauterine Contraceptive Devices, **TCu 380 Plus**

Manufacturer: SMB Corporation of India
Manufacturer's Address: 13, 33-36, Prem Industrial Estate,
Jogeshwari (E), Mumbai – 400 060, India
Tel: 91 22 28246922, 28345637 Fax: 91 22 28215157
Email: sales@smbcorpn.com **Website:** www.smbcorpn.com

Declaration of Conformance:

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 7439:2015 Standard as applicable

Certificate No. : 239347-2017-CE-IND-NA-PS rev 3.0

Notify Body: DNV GL Presafe AS. Notified Body No. 2460

Address of Notify Body: Veritasveien 3, N-1363 Hovik, Norway..

Validity of Certificate: 27.02.2024

Manufacturer's authorized representative in EC:

Obelis s.a
Boulevard General Wahis 53
1030 Brussels, Belgium
Tel: +(32) 2 732 59 54. Fax: +(32) 2 732 60 03.
Email : mail@obelis.net

Date of Signature: 30.04.2019



Mr. Anupam Rai
Chief QA & CS
SMB Corporation of India