

UNFPA Prequalified TCu380A IUD Manufacturers (in alphabetical order)ⁱ

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This list contains TCu380A IUD manufacturing sites that have been found to meet the requirements of the TCu380A Intrauterine Contraceptive Device (IUD) WHO/UNFPA Technical Specification and Prequalification Guidance, 2016

Manufacturer	Product	Country	Prequalified Manufacturing Site*	Most Recent Year of Inspection ⁱⁱ
1 Corporate Channels India Pvt Ltd	TCu380A	The Republic of India	1590-1600, Village Paldi, Lator, P.O. Badgaon, Udaipur 313001, Rajasthan	2019 ⁱⁱⁱ
2 HLL Lifecare Ltd	TCu380A	The Republic of India	Akkulam Plant, Sreekaryam P.O. Thiruvananthapuram 695 017, Kerala	2019 ⁱⁱⁱ
3 Injeflex Industria E Comercio Ltd	TCu380A	Brazil	Rua Cipriano Barata 575, Sao Paulo 04205-000	2017
4 Meril Endo Surgery Pvt Ltd	TCu380A	The Republic of India	Third Floor, E1-E3, Meril Park Survey No 135/2/B & 174/2 Muktanand Marg, Chala,Vapi 396191, Gujarat	2018
5 Pregna International Ltd	TCu380A	The Republic of India	Plot No. 219 Survey No. 168; Dabhel Co-op. Ind Soc Ltd. Dabhel, Daman 396 210, Gujarat	2019 ⁱⁱⁱ
6 SMB	TCu380A	The Republic of India	SMB Corporation of India Prem Industrial Estate, Subash Road, Jogeshwari (East), Mumbai 400 060, Maharashtra	2019 ⁱⁱⁱ
	TCu380A	The Republic of India	SMB Medical Devices Pvt. Ltd 156 GIDC. Dist. Valsad, Umbergaon	2019 ⁱⁱⁱ

ⁱ Manufacturers may have many manufacturing sites. This list reflects the specific manufacturing site that has been evaluated or undergoing reassessment as part of the prequalification process and is currently prequalified.

ⁱⁱ Prequalified products and the respective manufacturing site must undergo a requalification process every 3 years to maintain prequalification status.

ⁱⁱⁱ Undergoing prequalification reassessment. Remains listed until found to not meet requirements during reassessment. Pending CAPA submission period extended due to COVID-19 pandemic