

# UNFPA Prequalified TCU380A IUD Manufacturers (in alphabetical order)<sup>i</sup>

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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 <sup>ii</sup>	Annual Production Capacity (Approximate)
1	Corporate Channels India Pvt Ltd	TCu380A	The Republic of India	1590-1600, Village Paldi, Layan, P.O. Badgaon, Udaipur 313001, Rajasthan	2019 <sup>iii</sup>	20.74 million pcs
2	HLL Lifecare Ltd	TCu380A	The Republic of India	Akkulam Plant, Sreekaryam P.O. Thiruvananthapuram 695 017, Kerala	2019 <sup>iii</sup>	5.5 million pcs
3	Injeflex Industria E Comercio Ltd	TCu380A	Brazil	Rua Cipriano Barata 575, Sao Paulo 04205-000	2017 <sup>iv</sup>	7.83 million pcs
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	3.75 million pcs
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	14.4 million pcs
6	SMB	TCu380A	The Republic of India	SMB Corporation of India Prem Industrial Estate, Subash Road, Jogeshwari (East), Mumbai 400 060, Maharashtra	2019 <sup>iii</sup>	12 million pcs
		TCu380A	The Republic of India	SMB Medical Devices Pvt. Ltd 156 GIDC. Dist. Valsad, Umbergaon	2019 <sup>iii</sup>	12 million pcs

<sup>i</sup> 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.

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

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

<sup>iv</sup> Prequalification on-site inspection is postponed due to COVID-19 pandemic.