

LOT 4: Copper TCU380A intra-uterine device (IUD) prequalification

Like the Prequalification Programmes for Male and Female Condoms, WHO has delegated the management of the Prequalification Programme for TCU380A IUDs to UNFPA while it maintains a normative role in setting norms and standards. UNFPA conducts the prequalification programme for TCU380A IUDs on behalf of other UN agencies and the prequalified factories are open to bid for tenders for UN agencies, national governments and NGO procurement that supply the public sector. The prequalification procedure is designed to assess the quality, safety, and manufacturing data of the product and the manufacturer to ascertain whether the manufacturer meets the requirements defined in the [WHO/UNFPA TCU380A Intrauterine Contraceptive Device \(IUD\): Specification, Prequalification, Guidance 2016](#) document and in compliance with the relevant international standards.

The prequalification process involves the following key stages for which the expertise of the consultants is required: review of submitted technical documentation for prequalification and factory inspection including product sampling. The prequalification process is detailed in pages 16-19 of [WHO/UNFPA TCU380A Intrauterine Contraceptive Device \(IUD\): Specification, Prequalification, Guidance 2016](#).

a. Background

Two key steps in the prequalification process are the technical assessment of documentation submitted by applicants and the on-site inspection that is conducted for applicants that have successfully passed the document review stage. The aim of the assessment of the documentation submitted for prequalification is to determine whether the applicant meets the minimum requirements set out in the relevant ISO standards and WHO/UNFPA Specification in respect of product quality and safety, production and quality management, regulatory approval and capacity of production. The aim of the on-site inspection is to assess the manufacturing process and the product and quality management systems for compliance with general and performance requirements of the WHO/UNFPA Specification and good management practices, and relevant international standards.

b. Document review for prequalification (product dossiers, site master files, regulatory approvals, certifications and licenses)

TCU380A manufacturers willing to be prequalified by UNFPA submit the following documentation:

- Product Dossier
- Site Master File
- Regulatory approvals/authorizations, manufacturing licenses
- Product certifications and quality management systems certifications
- Samples of the finished product

The document review should verify that the manufacturer meets all the requirements as detailed on pages 16-17 of the [WHO/UNFPA TCU380A Intrauterine Contraceptive Device \(IUD\): Specification, Prequalification, Guidance 2016](#).

c. Expected services and deliverables for document review

- Review applicant documentation provided electronically by UNFPA. The consultant shall critically assess the documentation in order to verify compliance with the requirements detailed on pages 16-17 and 57 – 65 of the [WHO/UNFPA TCU380A Intrauterine Contraceptive Device \(IUD\): Specification, Prequalification, Guidance 2016](#). The review shall be completed within two weeks of receipt unless otherwise agreed with UNFPA.
 - Review of all the basic information about the manufacturer regarding their regulatory and legal standing as a manufacturer in the country they operate in.
 - Review and verification of all the certifications, licenses, approvals submitted.
 - Detailed assessment and review of all the technical data/documents on product safety, manufacturing process, risk management (Product Dossier and Site Master File) including the production capacities.
- Preparation of a document review report that can be presented to the prequalification applicant and includes a clear summary of recommendations from the review outlining next steps for factory inspection if requirements have been met and any follow ups/verifications that should be done during inspection. The document review report shall be prepared in accordance with the document review templates.

To see the template to be used, refer to *Template IUD* attached under the tender notice. It is provided for reference purposes. UNFPA reserves the right to modify the templates during the course of the LTA.

- Conduct document reviews of manufacturer and/or product reports as requested.

Submissions that are found to meet the minimum requirements after document review proceed to factory inspection.

d. Factory inspections and product sampling of TCU380A products for prequalification testing (Lead Inspector and Co-Inspector capacities)

The scope of the prequalification factory inspection goes beyond the ISO 13485 audit and covers more rigorous inspection that places heavy emphasis on both documentation and product manufacturing processes. The factory inspection is conducted over a period of 2 days by a technical team consisting of the Lead-inspector, Co-inspector, a UNFPA staff member, and may include representative from a local or international regulatory authority as well as an interpreter/translator if applicable.

The Lead Inspector and Co-Inspector will take the lead in the technical inspection of the factory to cover all manufacturing processes, quality management procedures, technical files, quality control facilities, processes and procedures. The UNFPA staff member will accompany the inspectors as part of the inspection team to assess other elements of the factory in line with UN mandate e.g human rights and environmental issues.

e. Expected services and deliverables for factory inspection and product sampling

- Develop an inspection programme for submission to UNFPA two weeks in advance of any scheduled inspection.

- Conduct on-site factory inspection in capacity of either Lead Inspector or Co-Inspector covering the following in line with the requirements detailed in the [WHO/UNFPA TCu380A Intrauterine Contraceptive Device \(IUD\): Specification, Prequalification, and Guidelines 2016](#). and supporting guidelines which includes:
 - General overview of the factory, infrastructure, human resources, quality management systems and production capacity
 - Material sourcing and handling, management and maintenance of equipment and technology for all the manufacturing processes,
 - Product quality records, quality control laboratory, internal quality control and final release processes, management and handling of rejections
 - Lot traceability, process control, validations, sampling and inspection plans
 - Product release and management of customers and supply chain processes
- Sampling of product of prequalification testing in accordance with requirements provided by UNFPA and ISO 2859-1.
- Provide a full inspection report in compliance with UNFPA’s templates for on-site inspections that includes an analysis of the test results from the Lots sampled during the inspection, summary of the overall outcome in relation to prequalification progress, a clear recommendation of next steps for the manufacturer and conclusions for UNFPA's review.
- Inspection reports are expected to be produced for UNFPA within four weeks subject to receipt of product testing results, unless there is a delay with the testing and new time period for the report to be completed is agreed upon between UNFPA and the inspector. The lead inspector is expected to sign the report that shall be prepared in accordance with UNFPA template.

To see the template to be used, refer to *Template IUD Inspection Report* attached under the tender notice. It is provided for reference purposes. UNFPA reserves the right to modify the templates during the course of the LTA.

- During the inspection, there may be non-conformities raised that require submission of evidence of corrective and preventive actions by the prequalification applicant. The Inspection Team shall be responsible for the evaluation of any corrective and preventive actions submitted for review.
- The **Lead-Inspector** is required to:
 - During the inspection, outline the inspection plan for the manufacturer and areas to be covered during the opening meeting and lead summary comments during the closing meeting.
 - Coordinate with the Co-Inspector any work performed remotely
 - Submit final assessment reports to the Prequalification Team within the timeline specified. In the event of disputes, provide resolution.
- The **Co-Inspector** is required to:
 - Work hand in hand with lead auditor and will focus on areas as outlined by the lead auditor

f. Minimum qualifications and experience

- For both Lead Inspectors and Co-inspectors, qualifications or training in any of the following fields: Chemistry, Biomedical, Biochemistry, Epidemiology, Biostatistics, Engineering, Pharmaceutical, Clinical Research, Microbiology, Public Health supported with knowledge and experience copper-bearing IUDs.
 - Additional points will be given for qualifications for ISO 14001 auditing.
 - Additional points will be given for experience with conducting WHO/UNFPA prequalification assessments.
 - Additional points will be given for ISO certification for performing ISO 13485 audits or GMP inspections with documented evidence of knowledge in copper-bearing IUDs.
 - Additional points will be given for previous experience in working with other international organizations and/or public sector entities.
 - For Lead Inspectors, additional points will be given for Lead Auditor certification for medical devices.

- For both Lead Inspectors and Co-inspectors, at least three completed projects each of similar nature and scope in various countries.
- For Lead Inspectors, at least 10 years of experience in one or more of the following: quality management systems for IUD manufacturing, IUD manufacturing production processes or inspections, clinical trial and review of clinical safety and efficacy data of IUD.
- For proposed Co-inspectors, at least 7 years of experience in one or more of the following: quality management systems for IUD manufacturing, IUD manufacturing production processes or inspections, clinical trial and review of clinical safety and efficacy data of IUDs.
- For both Lead Inspector and Co-inspector, fluency in English as demonstrated through previous formal training, qualifications, or work experience.
- For both Lead Inspector and Co-inspector, ability and willingness to travel, and willingness to comply with the travel arrangements as detailed in the respective section of the Terms of Reference document. Vast majority of inspections are in China, Malaysia, India and Thailand. A list of factory sites currently prequalified is published on www.unfpaprocurement.org
- For both Lead Inspectors and Co-inspectors, willingness to comply with UNFPA's prequalification confidentiality and conflict of interest rules.
 - Manufacturer's information
 - UNFPA's prequalification confidentiality and conflict of interest rules as detailed on page 15 of [WHO/UNFPA TCu380A Intrauterine Contraceptive Device \(IUD\): Specification, Prequalification, and Guidelines 2016](#).
- Willingness to work under a staff augmentation modality as described in the respective section of the Terms of Reference document.



END OF TERMS OF REFERENCE FOR LOT 4: COPPER TCU380A IUDS PREQUALIFICATION