

LOT 7: Medical equipment and consumables – technical evaluation of tenders, site assessments, product sample assessments, development of technical specifications, development of guideline documents, training, and workshop facilitation

a. Background

UNFPA procures medical devices in the following categories: Anaesthesia & resuscitation equipment, anatomical models, hospital equipment and furniture, medical diagnostic equipment and diagnostic supplies, medical & surgical instruments, sterile instruments, *in vitro* diagnostic devices and supplies, medical electrical & sterilization equipment, and medical utensils, supplies, attire and linen. To guide procurement decisions, the quality assurance work on medical devices is to ensure safe and good quality products are supplied by UNFPA. The quality assurance processes are to assess that the products conform to generic specifications and international safety standards.

b. Expected services and deliverables

- Assessment of technical documents related to medical devices and device suppliers for bid/tender evaluations including clear reporting of the performed evaluation work.
- Site assessments for physical inspection of products or assessment of product samples.
- Drafting of technical specifications and development of technical and/or policy and guideline documents commissioned by UNFPA within the time frame agreed between the two parties - including any necessary research, desk reviews and analysis, using latest available scientific data.
- Training and workshop facilitation at technical meetings including development of training material and presentations.

c. Minimum qualifications and experience

- For each of the proposed consultants, qualifications or training in any of the following fields: biomedical engineering, biomedical technology, medicine, medical or biomedical research, medical device manufacturing, quality engineering with focus on medical devices or related field.
- For each of the proposed consultants, knowledge and at least 7 years of experience in all of the following:
 - Knowledge and experience in the management and use of medical devices in health care services
 - Knowledge and experience with medical devices and RH commodities included in or similar to UNFPA's portfolio (available here: <https://www.unfpaprocurement.org/products>)
 - Knowledge of regulatory context for medical devices



- Knowledge in drafting and reviewing specifications, technical documents, safety standard documents for bid evaluation, and expertise in health technologies specifically in medical devices
- Additional points will be given for:
 - Experience in performing research, guideline development or conducting trainings especially on behalf of another UN agency, international organizations, and/or public sector entities
 - Experience related to the existing product groups listed in UNFPA medical devices.
 - ISO 13485 and/or ISO 9001 QMS certification.
 - Qualifications for ISO 14001 auditing
 - Any additional international accredited certification relevant to auditing medical devices
- For each of the proposed consultants, at least 3 completed projects of similar nature and scope in various countries, including experience in conducting technical evaluations of tender processes for medical devices
- For each of the proposed consultants, fluency in English as demonstrated through previous formal training, qualifications, or work experience.
- For each of the proposed consultants, 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.
- For each of the proposed consultants, willingness to comply with UNFPA's confidentiality and conflict of interest rules.
 - Confidentiality of manufacturer's information
 - During technical evaluation of tenders, confidentiality of proposals and confidentiality of procurement process
 - During technical evaluation of tenders, compliance with no-conflict-of-interest rules for technical evaluation committee members
- 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 7: MEDICAL EQUIPMENT AND CONSUMABLES