OFFERED ITEM OVERVIEW FORM

UNFPA.MNG.RFQ.24.008

Name of Bidder: …………………………………..

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| **№** | **Item name** | **Requirement for products** | **Quantity** | **(To be completed by Bidder)**  **Is bid compliant?** | **(To be completed by Bidder)**   1. Name of manufacturer, product model. 2. Please provide detail of the offered product against the requirements of UNFPA. 3. Bidder’s statements on deviations if any. |
| 1 | IUD removal hook | **Product Description**  The Universal IUD Hook is a medical instrument designed for intrauterine device (IUD) insertion and removal procedures. The instrument is atraumatic, ensuring minimal tissue damage and patient discomfort during procedures. Its curved design allows for optimal access and maneuverability within the uterine cervix. Classified under EU MDR 2017/745 as Class I device  **Technical specifications:**   * **Material:** High-grade stainless steel (AISI 304) * **Total Length:** 10 inches (25 cm) * **Hook Diameter:** 4 mm * **Design:** Curved for enhanced access and maneuverability, smooth, polished surface to prevent tissue trauma. * **Ergonomics:** Handle designed for a comfortable grip and precise control * **Sterilization:** Autoclavable, compatible with standard sterilization procedures. * **Packaging & Labelling**:   + Single unit packaging or kit packaging with Symbols used according to ISO 15223.   + Labelling as per regulations applied to the device. Shall include name of the device, name and address of the manufacturer, product code or manufacturers reference number.   **Documentation requirement:**   * Instructions for Use (IFU) should be provided with comprehensive instructions on the use, cleaning, disinfection and sterilization methods and types for the product. * Warranty Certificate: At least one-year warranty covering manufacturing defects. * Manufacturing license   **Regulatory approvals required:**   * CE mark Comply to EU Council Directive 93/42/EEC (MDD) or EU Regulations 2017/745 (MDR) with valid EC Certificate and Declaration of Conformity for the CE mark is applicable. * ISO 13485 Medical Devices - Quality Management Systems * ISO 14001 Environmental Management * ISO 50001 Energy Management Systems   **Safety & product Standards**  Must comply with the following standards (as per latest revisions of the standards):   * ISO 7153-1:1991 Surgical Instruments – Metallic Materials * ISO 17664:2004 Sterilization of Medical Devices - Information to be Provided by the Manufacturer for the Processing of Resterilizable Medical Devices * ISO 13402:1995 Surgical and Dental Hand Instruments - Determination of Resistance Against Autoclaving, Corrosion, and Thermal Exposure | 24 | Yes  No |  |
| 2 | Medical instruments for vasectomy set | **Product Description**  A vasectomy set typically includes a range of specialized instruments designed to facilitate the vasectomy procedure, which is a form of male sterilization.  **Technical specifications:**   1. **Scalpel Handle and Blades**    * **Scalpel Handle:** Size 3, made of stainless steel AISI 304.    * **Scalpel Blades:** Size 10 or 15, sterile and disposable. Stainless steel AISI 420. 2. **Straight Hemostatic Forceps**    * **Type:** Mosquito forceps    * **Size:** 5 inches (12.5 cm), straight    * **Material:** Stainless steel AISI 410, atraumatic, serrated tips 3. **Curved Hemostatic Forceps**    * **Type:** Kelly or Crile forceps    * **Size:** 5.5 inches (14 cm), curved    * **Material:** Stainless steel AISI 410, atraumatic, serrated tips 4. **Ring-Tip Forceps**    * **Type:** Ring-tipped (also known as Allis forceps)    * **Size:** 5.5 inches (14 cm)    * **Material:** Stainless steel AISI 410, atraumatic, with fine tips for grasping the vas deferens 5. **Needle Holder**    * **Type:** Mayo-Hegar or similar    * **Size:** 5 inches (12.5 cm)    * **Material:** Stainless steel AISI 410, with a locking mechanism 6. **Suture Scissors**    * **Type:** Straight or curved surgical scissors    * **Size:** 4.5 inches (11.5 cm)    * **Material:** Stainless steel AISI 420 or 440, fine tips 7. **Iris Scissors**    * **Type:** Curved or straight    * **Size:** 4.5 inches (11.5 cm)    * **Material:** Stainless steel AISI 420 or 440, fine tips 8. **Vasectomy Clamp**    * **Type:** Ringed clamp or No-Scalpel Vasectomy (NSV) clamp    * **Size:** Varies, typically 5-6 inches (12.5-15 cm)    * **Material:** Stainless steel AISI 410, designed to securely hold the vas deferens during the procedure 9. **Dissecting Forceps**    * **Type:** Adson forceps with teeth or without teeth    * **Size:** 4.75 inches (12 cm)    * **Material:** Stainless steel AISI 410, fine tips for precise tissue handling 10. **Vasectomy Hook**     * **Type:** Curved hook     * **Size:** 5 inches (12.5 cm)     * **Material:** Stainless steel, atraumatic   **Documentation requirement:**   * Instructions for Use (IFU) should be provided with comprehensive instructions on the use, cleaning, disinfection and sterilization methods and types for the product. * Warranty Certificate: At least one-year warranty covering manufacturing defects. * Manufacturing license   **Regulatory approvals required:**   * CE mark Comply to EU Council Directive 93/42/EEC (MDD) or EU Regulations 2017/745 (MDR) with valid EC Certificate and Declaration of Conformity for the CE mark is applicable. * ISO 13485 Medical Devices - Quality Management Systems * ISO 14001 Environmental Management * ISO 50001 Energy Management Systems   **Safety & product Standards:**  Must comply with the following standards (as per latest revisions of the standards):   * ISO 7153-1:1991 Surgical Instruments – Metallic Materials * ISO 17664:2004 Sterilization of Medical Devices - Information to be Provided by the Manufacturer for the Processing of Resterilizable Medical Devices * ISO 13402:1995 Surgical and Dental Hand Instruments - Determination of Resistance Against Autoclaving, Corrosion, and Thermal Exposure | 2 |  |  |
| 3 | Vasectomy training model | **Product Description**  A vasectomy training model, that simulates an adult male genital structure, with a realistic shape and texture, designed for no-scalpel vasectomy operation training.  The vasectomy model grants the development of competence-based training sessions, allowing practice and learning skills to develop no-scalpel vasectomy.  **Technical specifications:**   * Anatomical model composed by:   + *Male torso section*, modeling lower abdomen to above-knee stump.   + *Removable scrotal skins*.   + *Testicle assembly* with tubing attached, simulating the vas deferens. * External skin tone: light to medium skin tone. * Male torso section, with at least four (4) anti-slip feet/pads. * Removable scrotal skin, flexible and penetrable to be pierced and to access the vas deferens simulation tubing. * Male torso section, Removable scrotal skin and Testicle assembly must be built of materials resistant to the application of disinfectants commonly used in healthcare premises, i.e.: 70% isopropyl alcohol.   **Accessories:**   * Two (2) reusable removable scrotal skins   + One (1) included in the standard configuration.   + The rest to be used as spare parts. * Two (2) reusables set of two testicle assemblies   + One (1) set included in the standard configuration.   + The rest to be used as spare parts. * Two (2) sets of vas deferens simulation tubing with securing/fastening mechanism.   + One (1) included in the standard configuration.   + The rest to be used as spare parts.   **Documentation requirement:**   * Bidders shall furnish the following documents as a part of the Bid, in English language:   + Manufacturer brochure or data sheet including at least all technical specifications required.   + Instructions for use including procedures for cleaning, disinfection and storage conditions.   + List of all common spare parts and accessories with part numbers.   + Manufacturer authorization letter.   + Manufacturer letter of commitment including:     - Installation and commissioning on site would be performed by the manufacturer or the representative in the country.     - At least one (1) year of full onsite warranty.     - At least five (5) years of spare parts availability.     - Training on use, cleaning and disinfecting for the healthcare staff, in Mongolian language. * Bidders awarded, during the commissioning shall deliver the following documents, in English, Mongolian and/or another requested language:   + Instructions for use including procedures for cleaning, disinfection and storage conditions.   + List of all common spare parts and accessories with part numbers.   + Warranty certificate.   + Manufacturer letter with at least five (5) years of spare parts availability.   **Regulatory approvals required:**   * Bidders shall furnish the following documents as a part of the Bid:   + Valid manufacturing license, issued by the corresponding authority in the manufacturing country.   **Safety & product Standards:**   * Valid ISO 9001, Quality management systems certificate, issued by Conformity assessment bodies, notified bodies or by bodies accredited by regulatory authorities. | 2 | Yes  No |  |
| 4 | Multi-purpose uterus model (IUD insertion, removal) | **Product Description**  An uterus training model, that simulates an adult female genital structure, with a functional shape and texture, is designed for multi-purpose training.  The uterus training model grants the development of competence-based training sessions, allowing practice and learning skills to develop skills like vaginal examination, pap smear sample collection, IUD insertion, removal of retained products of conception by using manual vacuum aspiration (MVA).  **Technical specifications:**   * Model representing female abdominal section. * Design allows configuring the model in two modes:   + Simulation, to be fastened around the body of a person.   + Training, to be used as a standalone educational material. * Inside the model, the uterus is adjustable allowing it to be configured in a retroverted and anteverted angles. * At least two sized uterus:   + Small, representing an early post-abortion uterus.   + Large, representing a large uterus like a multiparous and/or a post abortion uterus. * Must be built of easily cleanable materials.   **Accessories:**   * One (1) carrying case, from the same manufacturer or expressly recommended by the manufacturer of the multi-purpose uterus model. * One (1) strap to fasten the model around the body. * One (1) system or device to keep the multi-purpose uterus model in position during training sessions.   **Documentation requirement:**   * Bidders shall furnish the following documents as a part of the Bid, in English language:   + Manufacturer brochure or data sheet including at least all technical specifications required.   + Instructions for use including procedures for cleaning, disinfection and storage conditions.   + List of all common spare parts and accessories with part numbers.   + Manufacturer authorization letter.   + Manufacturer letter of commitment including:     - Commissioning on site would be performed by the manufacturer or the representative in the country.     - At least one (1) year of full onsite warranty.     - At least five (5) years of spare parts availability.     - Training on use, cleaning and disinfecting for the healthcare staff, in Mongolian language. * Bidders awarded, during the commissioning shall deliver the following documents, in English, Mongolian and/or another requested language:   + Instructions for use including procedures for cleaning, disinfection and storage conditions.   + List of all common spare parts and accessories with part numbers.   + Warranty certificate.   + Manufacturer letter with at least five (5) years of spare parts availability.   **Regulatory approvals required:**   * Bidders shall furnish the following documents as a part of the Bid:   + Valid manufacturing license, issued by the corresponding authority in the manufacturing country.   **Safety & product Standards:**   * Valid ISO 9001, Quality management systems certificate, issued by Conformity assessment bodies, Notified bodies or by bodies accredited by regulatory authorities. | 6 | Yes  No |  |

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