# Annex. 4
# PRODUCT SPECIFICATIONS AND TECHNICAL REQUIREMENTS

THIS DOCUMENT IS TO PROVIDE THE OFFERORS WITH THE PRODUCT(S) SPECIFICATIONS AND TECHNICAL REQUIREMENTS FOR THE PROCUREMENT OF COMMODITIES LISTED IN THE RFQ: **GHSC-PSM-TO3-2018-IUD-IDIQ**

## I. Product Specifications

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| Category: Type | Intrauterine Device (IUD): Single-use, sterilized copper-bearing intrauterine contraceptive device (TCu380A) and the insertion instrument |
| Product Components | TCu380A IUD and insertion instrument |
| Materials | **T-Frame:** The frame shall be made from Low Density Polyethylene (LDPE), free of stabilizers, having a minimum tensile strength of 13 MPa. The LDPE shall be blended with 15% to 25% precipitated barium sulphate USP (United States Pharmacopeia) with a particle size of 95% less than 10 micron. The barium sulphate content of the frame material shall be determined according to the relevant clause of ISO 7439.<br><br>**Copper Wire:** The wire shall be made from oxygen-free electronic (OFE) 99.99% pure copper meeting National Bureau of Standards designation UNS C10100. There shall be no coating on the wire.<br><br>**Copper Collars:** The copper collars shall be made from half-hard temper, seamless copper tube made from OFE 99.99% pure copper meeting the National Bureau of Standards designation UNS C10100. There should be no coating on the collars.<br><br>**Thread:** The thread shall be monofilament made from High-Density Polyethylene (HDPE), free of stabilizers, with a sufficient minimum tensile strength to produce a thread meeting the specified strength requirement (9.5 Newton). A material with a minimum tensile strength of 28 MPa is recommended. The thread polymer shall be compounded with 0.4% up to 1.0% by weight USP (EP) rutile titanium dioxide.<br><br>**Insertion Tube:** The tube shall be made from food contact grade HDPE (High Density Polyethylene).<br><br>**Insertion Rod:** The rod shall be made from food contact grade radiation stable ABS (acrylonitrile-butadiene-styrene polymer) or food contact grade radiation-stabilized polypropylene (PP).<br><br>**Positioning Flange:** The flange shall be made from a suitable polymer with adequate radiation stability to function mechanically post-sterilization. |
| Biocompatability | The compounded T frame polymer (LDPE plus barium sulphate) and compounded thread as an assembly, or separately shall be evaluated for biological safety in accordance with ISO 10993-1 requirements for mucosal membrane contact devices intended for permanent contact. |

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| | Specifically, the following is required:<br>-Evaluation for genotoxicity according to ISO 10993-3<br>-Evaluation for cytotoxicity according to ISO 10993-5<br>-Evaluation for local effects after implantation according to ISO 10993-6<br>-Evaluation for irritation and delayed-type hypersensitivity according to ISO 10993-10<br>-Evaluation for subacute and subchronic toxicity according to ISO 10993-11<br><br>Testing must be performed by a laboratory that is accredited to ISO 17025 with IUD testing included in the scope of accreditation.<br><br>For a specific material, it is only necessary to carry out the assessment of biological safety once. The evaluation shall be repeated if there is a significant change to the materials, for example, if the grade or supplier is changed.<br><br>Manufacturers may continue to use DuPontTM 20 LDPE and Phillips 6007 HDPE without conducting the biocompatibility evaluation on the T frame compound with barium sulphate or thread compound with titanium dioxide.<br><br>It is required that all biological safety tests in accordance with ISO 10993 parts 1, 3, 5, 6, 10 and 11 be conducted by laboratories accredited for these tests. |
| Sterilization | The TCu380A IUD shall be supplied sterile in a sealed primary pack together with the insertion tube, the insertion rod and the positioning flange. Sterilization shall be by radiation according to ISO 11137 series, or by ethylene oxide according to ISO 11135 series and standards normatively referenced therein.<br><br>Radiation sterilization is preferred, to allow the use of continuous polymer film packaging materials.<br><br>The sterilization shall be completed within 30 days of sealing the finished device in the pouch.<br><br>The sterilization assurance level shall be $10^{-6}$.<br><br>If ethylene oxide sterilization is used, then residual ethylene oxide levels shall not exceed 10 ppm, and ethylene chlorohydrin levels shall not exceed 20 ppm, on any individual Sample when measured using a method that complies with the requirements of ISO 10993-7. Average residual levels across all samples tested shall not exceed 5 ppm for ethylene oxide and 10 ppm for ethylene chlorohydrin. |
| Target Population | Women of Reproductive Age |
| Use | Single Use |
| Storage Conditions | Real time studies are always required and accelerated studies may be submitted prior to the real time studies being available, the real time studies being conducted at (30 ± 2) °C and (75 ± 5)% relative humidity to model the most extreme storage conditions (climatic zone IVb, hot humid/tropical) |
| Shelf-life | Minimum 84 months shelf-life and a maximum in-situ time of 12 years. |
| Primary Packaging | Packaging materials shall comply with ISO 11607-1. Polymer films, preferably continuous, shall be used to reduce the risk of tarnishing of the copper. The primary package container requires a measured ruler card to aid proper insertion. |

## II. General Product Requirements

The following general product requirements apply to this solicitation for copper-bearing intrauterine contraceptive devices (TCu380A):

- Products offered must be SRA* cleared/approved, CE Mark and listed on the WHO/UNFPA Prequalification Program for TCu380A IUDs.
- Products offered should be manufactured in accordance with ISO 7439: 2015.
- Manufacturer must have a Quality Management System in place with evidence of ISO 13485 certification (current valid certificate from an accredited body).
- Products offered must have a minimum of 84 months shelf life (7 years), in accordance with ICH guidelines and as supported by adequate stability data, to support transport and storage in Climatic Zone IVb (30 °C/75% RH). Recommended storage conditions and shelf life should be clearly indicated on the product labeling for all components.
- The product labeling, physician leaflet, and patient information shall be available at minimum in English language. The Offeror will be responsible for the preparation and availability (including regulatory approval) of French, Portuguese, Spanish and other languages that may be required and as directed by GHSC-PSM.

**USAID recognized stringent regulatory authorities (SRA): U.S. Food and Drug administration (USFDA), Japanese Ministry of Health, Labor, and Welfare (MHLW), also represented by the Pharmaceuticals and Medical Devices Agency (PMDA); European Medicines Agency (EMA) and member states admitted to the European Union (EU) prior to 1996 Hague Convention (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, and United Kingdom); SwissMedic; Health Canada; and Australia Therapeutic Goods Administration (TGA).*

## III. Conformity with Quality and Products Standards

Pharmaceuticals procured using US Government funds under the Global Health Supply Chain Program – Procurement and Supply Management (GHSC-PSM) project are restricted commodities and must comply with the guidance as indicated under ADS 312 from the United States Agency for International Development (USAID) Global Health Bureau. The vendor guarantees that the offered items are compliant with the USAID guidance for Pharmaceuticals ADS 312.
https://www.usaid.gov/sites/default/files/documents/1864/ADS312AdditionalHelpDocument.pdf

## IV. Quality Assurance Provision

Manufacturer shall coordinate with GHSC's quality assurance contractor, Global Health Supply Chain Program - Quality Assurance (GHSC-QA), who will implement inspection, sampling, quality assurance testing and acceptance within the terms and conditions outlined in the contract.

## V. Pre-Acceptance Sampling and Testing requirements

Offeror shall provide requested product documentation for review and acceptance prior to shipment. GHSC-QA reserves the right to sample from the Manufacturer's facility and to perform or cause to be performed any of the tests and inspections set forth in this purchase description to assure that supplies and services conform to the prescribed requirements.

Products may be pre-shipment sampled and tested.

A Manufacturer Certificate of Analysis is required for all lots procured.

## VI. Sampling requirements

The Manufacturer shall advise GHSC-QA when the completed production is ready for sampling. Samples shall be drawn only from finished product which has been tendered for acceptance.

The entire production shipment shall be quarantined until testing has been completed and disposition rendered. One hundred (100) percent of the lots shall be sampled and evaluated for acceptance. The Manufacturer can provide the lot sample, as the IUD manufacturing process and sterilization steps creates a true random sample. At the time of sampling, the Manufacturer shall supply GHSC- QA with the original finished laboratory product test results for each sampled lot.

The Manufacturer's physical test data shall be on record for each lot shipped to GHSC-PSM and shall be available to GHSC-QA upon request for a length of time equal to seven (7) years from the time of acceptance.

## VII. Test method

Test methods used in product evaluation and their respective acceptance criteria will be those specified by the current edition of ISO 7439 and as listed in Table I-A, I-B and I-C.

**Performance Tests.**
Test methods used in product evaluation and their respective acceptance criteria will be those specified by the current editions of ISO 7439, WHO/UNFPA TCu380A Intrauterine Contraceptive Device (IUD) Procurement Specification and as listed in Table 1-A.

**Product Defects.**
IUDs shall be selected at random from each lot for determination of compliance with the requirements specified in Table I-B. IUDs will be examined for defects in materials, construction, packaging, labeling, and overall serviceability using the description of possible defects in Table II-C. Note: The list of defects in Table I-B is not an exhaustive list. Other visible workmanship defects identified during the inspection process may be determined to detract from the physical appearance of the IUD or affect its usability.

**Table I-A**
**WHO/UNFPA: 2016 – Sampling sizes and acceptance criteria for testing**

| Continuing series of Lots | | | |
|---|---|---|---|
| **Requirement** | **Specification** | **Sample Size (pieces)** | **Max Permitted Nonconforming Units per Sample** |
| Frame Dimensions | | | |
| Length horizontal arms | 31.5 - 33.0 mm | 8 | 0 |
| Length vertical stem | 35.5 - 37.0 mm | | |
| Diameter of horizontal arm | 1.5 - 1.7 mm | | |
| Diameter of vertical stem | 1.4 - 1.6 mm | | |
| T piece ball diameter | 2.3 - 3.7 mm | | |
| Thread Length | 105 mm - 125 mm | | |
| Copper Collars | | | |
| Position from end of arm | 5.0 - 5.8 mm | 8 | For Information Only |
| Weight | 65.7 - 71.7 mm | 8 | 0 |
| Copper Collar Retention force | ≥ 6.86 N | | |
| Copper Wire | | | |
| Copper wire weight | 165 - 187 mm | 20 | 0 |
| Copper wire winding | single or doublewound | 8 | 0 |
| Insertion Tube | | | |
| Length | 204 - 208 mm | 8 | 0 |
| Internal diameter | 3.6 - 3.9 mm | | |
| External diameter | 4.3 - 4.6 mm | | |
| Insertion rod dimensions | | | |
| Length | 185 - 195 mm | 8 | 0 |
| Diameter at tip | 2.4 - 2.8 mm | | |
| Fit in insertion tube | no defects | | |
| Breaking strength | > 9.5 N | 13 | 0 |
| Memory | ≤ 5.0 mm | 8 | 0 |
| Flange displacement force | 2.0 - 9.0 N | 8 | For Information Only |
| Packaging | | | |

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| Sealed pouch integrity (Jan 1, 2018 onward) | Identify the presence of holes/voids in packages | 125 | 0 |
| Sealed pouch peel strength | | | |
| End seal | 4.4 - 19 N | 13 | 0 |
| Side seal | | | |
| Product Defects | | | |
| Defects (including knot security) | Void of visual defects | 50 | 0 |
| Individual pouch | Void of visual defects | 13 | 0 |
| Inner box(if consignment includes less than 13 inner boxes, inspect all boxes) | | | |
| Exterior shipping carton (if consignment includes less than 13 exterior shipping cartons, inspect all boxes) | | | |

## Table I-B Product Defects

**Product Defects (IUDs) (not an inclusive list)**

- Severe tarnishing of the copper collars or wire
- Missing components and/or empty pouch
- Flash on the mold lines of the T frame
- Sharp protruding edges and/or burrs
- Unsecured or missing thread (including loose or unsecure knot)
- Incomplete/deformed ball
- Deformed or loose collars
- Improperly sealed pouches
- Embedded and/or surface foreign particles on any component within the sealed pouch  Transfer of any printing onto the device
- Insertion rod bent or distorted (acceptable at the discretion of the purchaser if still usable)
- Discoloration of insertion tube or rod

## Table I-C Packing Defects

**Individual Pouch and Insert Defects (not an inclusive list)**

- Discolored film and labels
- Missing or incorrect labelling information
- Pouch with open or damaged seals
- Unclear and not readily legible printing on individual pouch and insert

**Inner-box Defects (not an inclusive list)**

- Damaged boxes that may affect the integrity, quality or distribution of the IUDs inside
- Empty or partially filled inner boxes
- Missing or incorrect labelling information
- Unclear and not readily legible printing on inner box

**Shipping Carton Defects (not an inclusive list)**

- Damaged shipping cartons that may affect the integrity, quality or distribution of the IUDs inside
- Empty or partially filled exterior shipping cartons.
- Missing or incorrect labelling information as specified in Clause 5.5
- Unclear and not readily legible printing on exterior shipping cartons **Table II-A**

**Compilation of Data.**
At the completion of testing, all data from the designated testing laboratory shall be sent to GHSC-QA for verification and comparison with original test data obtained from the Manufacturer.

**Lot Disposition.**
The recommendation to GHSC-PSM the disposition of tested lots shall be determined by the results of tests performed by the designated testing laboratory. The testing provisions of the contract shall be applicable. GHSC-QA will inform the Manufacturer and GHSC-PSM of any tested and quarantined lots that are unacceptable for delivery; conduct failure investigations, and coordinate any re-tests (if appropriate).

**Frequency of Monitoring.**
GHSC-QA may increase or decrease the frequency of monitoring and level of testing when warranted by either a significant change in quality or at the sole discretion of GHSC-QA. The purpose is to maintain an acceptable level of confidence in compliance with contract requirements.

**Manufacturer Furnished Inspection Data**
GHSC-QA will require that the Manufacturer provide a summary of the final inspection results for each lot available for delivery under this contract prior to shipment to GHSC-PSM. This summary shall include test results for all product attributes including sterilization date and packaging/foiling line. Individual test reports shall be maintained by the Manufacturer, and shall be made available for inspection by GHSC-QA.

## VIII. Post-Acceptance inspection

Unless otherwise specified in the Subcontract, each product lot delivered to GHSC-PSM shall comply with all product specifications and test procedures in effect at the time of subcontract award.

At any time within the 84-month shelf-life of the product, GHSC-QA and GHSC-PSM retain the right to re-examine any lot of IUDs in accordance with GHSC-PSM contractual Terms and Conditions. In such an event, the quality assurance and testing provisions of the contract shall be those in effect at the time the IUDs in question were accepted. If the complete IUD manufactured lot is not available at the field location, a sampling plan using the total lot inventory at the field location shall be implemented in determining the appropriate random sample numbers for testing in lieu of the original manufacturer's lot size.

If the independent testing proves the product to be defective and the Manufacturer does not provide GHSC-QA contradictory test data within 15 calendar days, or such longer period as may be approved by GHSC-QA, then GHSC-PSM reserves the right to abide by the independent testing and will proceed with disposition and replacement of defective product by the Manufacturer at no cost to GHSC-PSM.

**Participation in Proficiency Trials.**
The Manufacturer will agree to participate in one or more IUD proficiency trials (if available) each year of the contract.

## IX. Product documentation

The following product documentation is required **from manufacturers for direct procurement** as part of this solicitation:

- Completed Supplement 1 Medical Device Product Questionnaire for each product/presentation offered in accordance with the instructions provided. [Please see Supplement 2 Instructions for Creating a GHSC-QA Technical Questionnaire Submission and Supplement 3 Instructions to Access and Upload Documentation to GHSCQA SharePoint Site].

**All manufacturers are required to upload the completed Medical Device Product Questionnaire per instructions provided.**

## X. Shelf life

As stated above, products offered must have a minimum of 84-month shelf life, in accordance with ICH guidelines and as supported by adequate stability data, to support transport and storage in Climatic Zone IVb (30 °C/75% RH). Recommended storage conditions and shelf life should be clearly indicated on the product labeling for all components.

All goods must be freshly manufactured, and thus have maximum possible shelf-life. Goods should have 85% shelf-life remaining when delivered.

For products offered from stock offerors must clearly indicate the manufacturing date and expiry date.

# XI. Packaging and Packing

Product to be supplied under this contract will be packed and protected to prevent damage or deterioration during transportation and storage. The box will be manufactured of a standard heavy-duty material appropriate for the destination countries where high heat and humidity is prevalent, that will withstand export handling and rough treatment, and ensure the safety, efficacy and quality of the product.

**Package Identification.**

Individual pouches, sometimes referred to primary or individual packaging, are the protective packaging in which the products are provided. The IUDs are sealed into the individual pouches prior to sterilization.

**Packaging and Packing**

Packaging materials shall comply with ISO 11607-1. Polymer films, preferably continuous, shall be used to reduce the risk of tarnishing of the copper. **The primary package container requires a measured ruler card to aid proper insertion.**

Labeling shall be in accordance with ISO 7439 – "Copper-bearing Intrauterine Contraceptive Device – Requirements tests" for primary and secondary containers. Instructions of use and information intended for woman shall be in accordance with ISO 7439 and packaging must meet ISO 14630 – "Non-active surgical implants – General requirements". Packaging, packing and marking shall be in accordance with all applicable USFDA/SRA regulations.

**Barcoding**

GHSC-PSM will be implementing global standards for product identification, labeling, and data exchange. More information about this requirement can be found in Article 3 of the Terms and Conditions and the supplement titled *GHSC-PSM Global Standards Technical Implementation Guide*. In alignment with this requirement, please describe your current / planned capabilities and experience per the questions below (not to exceed 1 page).

GS1 Registration

- Is your organization currently registered with GS1? If yes, please provide your primary Global Location Number (GLN).

Global Data Synchronization Network (GDSN)

- Has your company filled out the GHSC-PSM GDSN Trading Partner Form[1]?
- Is your organization currently registered with a GDSN-certified data pool[2]? If not, please describe your plan to meet the GHSC-PSM data synchronization requirement by December 2019.

Product Identification & Labeling

- Please describe your current capabilities or plan to ensure that all products offered as part of this solicitation are assigned a Global Trade Item Number (GTIN).
- Please describe your current capabilities or planned approach to ensure that products offered as part of this solicitation are able to meet the applicable GHSC-PSM labeling requirement.

**Shipping Cartons:** Preference for range of 25 Sterilized Copper-bearing Intrauterine Contraceptive Device per inner carton, and 300 Sterilized Copper-bearing Intrauterine Contraceptive Device per shipping carton.

Twenty-five (25) sterilized Intrauterine Contraceptive Device individual packages shall be packed in a shelf storage container which will include twenty-five (25) patient information booklets and one (1) prescribing information booklet. Approved product labeling will appear on one face of this self-container.

Product labeling will appear on two adjacent faces of the inner carton.

## XII. USAID Marking requirements

Chemonics reserves the right to require USAID marking. The Manufacturer (s) will be responsible for ensuring that all export shipping cartons, whether shipped from the United States or from any other source country, carry the official USAID emblem, as necessary.

Emblems will be affixed by metal plate, decal, stencil, label, tag, or other means, depending upon the type of commodity or export shipping carton and the nature of the surface to be marked. The emblem on each export-shipping carton will be affixed in a manner which assures that the emblem will remain legible until the carton reaches the consignee. The size of an emblem will vary depending upon the size of the commodity and the size of the package or export-shipping carton. The emblem will, in every case, be large enough to be clearly visible at a reasonable distance.

Emblems will conform in design and color to samples available from USAID and can be found at: http://www.usaid.gov/branding/

Emblems will be obtained by the Manufacturer(s) at its expense in the quantity and type required. The Manufacturer(s) will be required to affix USAID emblems in accordance with the marking requirements stated above.