Section II: Evaluation Criteria

In evaluating each bid, UNOPS will follow the criteria and procedures described below.

1. General indications

1.1. About the evaluation methodology

The evaluation process will be carried out in stages under the following methodology:

- **First evaluation stage:**
    - **Evaluation of formal and eligibility criteria (preliminary examination of bids)**

      Compliance with Article 28 of the Instructions to Bidders section as detailed in 2.1 below will be verified. Bids that meet the formal, and eligibility criteria will proceed to the evaluation of the qualification criteria.

      The bids will be examined for apparent clerical errors, arithmetic errors will be corrected, and ties, if any, will be resolved. Then the bids will be ranked according to unit price.

    - **Evaluation of qualification criteria (bidder prequalification)**

      The evaluation of the bidder's capabilities will be carried out based on the review of the submitted documentation taking into account the criteria defined in section 2.2 below.

      Bidders who pass this evaluation will be accredited with the status of pre-qualified for future procurement processes for medicines and/or medical supplies; therefore UNOPS will notify in writing the outcome of the pre-qualification. Prequalified status does not necessarily mean that they will be invited to a limited competition as indicated in section 5.6 of the Procurement Manual version 7.

      Prequalification will be valid for 24 months from the date of notification. Bids that meet the qualification criteria will be eligible for the lot evaluation stage.

      Bidders who were prequalified in previous processes executed by UNOPS for the supply of medicines and/or medical supplies, and whose prequalification is still valid at the date of submission of bids do not need to be re-qualified.

      Upon completion of this first stage of evaluation; UNOPS will report the results of the evaluation of the preliminary examination of bids, and prequalification of the bidder. Only those bids that qualify after the preliminary bid review, and prequalification of the bidder will proceed to the next stage of evaluation.

- **Second evaluation stage (evaluation of bids by lot):**
    - **Evaluation of the qualifying administrative criteria:**

      This stage will be carried out in accordance with section 2.3 below:

        - Verification of quantities offered;
        - Verification of delivery plan/schedule

      The bids that meet the administrative criteria will be qualified to continue with the evaluation of technical criteria.

    - **Evaluation of the technical qualifying criteria**

      The technical evaluation of the bids will be carried out as indicated in section 2.4 below; according to the order of priority by unit price.

    - **Evaluation of complementary technical criteria**

      The offer with the lowest unit price that passed the evaluation of the technical qualification criteria will be submitted to the complementary technical evaluation as indicated in numeral 2.5 below.

- **Third evaluation stage (price and financial capacity evaluation):**

  The bids that pass the evaluation of the complementary technical criteria will be submitted to the price and financial capacity analysis as indicated in section 2.6 below.

UNOPS reserves the right to proceed or not with the full evaluation of the bid if within one of the stages the bidder fails to comply with one of the criteria requested in any of the evaluation stages indicated.

1.2. Award

UNOPS will award:

- Purchase Order for the quantities set forth in *Section III: Schedule of Requirements*, file Requerimiento por lote in the column *Cantidad segundo semestre 2022 a adquirir a través de Orden de Compra* and;
- Long Term Agreements (LTA) in order to be able to issue new purchase orders in the future if additional quantities are required to those contracted under this process. The estimated ~~minimum~~ quantity to be procured through an LTA is as indicated in Section III List of Requirements, file Requerimiento por lote, in the column *Cantidad estimada a adquirir año 2023 a través de LTA*.

The Purchase Order and the Long-Term Agreement will be the contractual documents governing this bidding process and may include one or more lots.

The award of the Contract/Purchase Order to each bidder shall be up to the limit of the bidder's financial capacity as defined in subsection 2.6 below of this section.

The Health/Sanitary Registration issued by COFEPRIS must be submitted no later than five (5) calendar days after notification of award. In case of failure to provide the Health/Sanitary Registration within the required deadline, UNOPS reserves the right to revoke the award.

Details on the contract template applicable to this process are available in *Section V: Contract Template*.

1.3 UNOPS right to change quantities

At the time of contract award, UNOPS reserves the right to modify (increase or decrease) the required quantity of one or more lots indicated in Section III: Schedule of Requirements by up to 20% (upward or downward), without any changes to the unit price of the affected lot(s) or other terms and conditions of the bid.

Any downward variation in excess of the UNOPS entitlement will be proposed to the bidder with the first-ranked bid of eligibility for the affected lot, allowing withdrawal of its bid, maintaining the bid, or submitting a counter-bid for the affected lot.

UNOPS reserves the right to accept or reject the counter bid submitted and to negotiate with the bidder whose bid has been evaluated as the second-lowest substantially compliant bid.

1.4. Joint Venture bids/offers

Different companies can partner to form a joint venture.

In order to submit a bid as a joint venture within the eSourcing platform; it is recommended to create a user ~~must be created~~ in UNGM in the name of the joint venture. In addition to this, each member must register in UNGM with the individual information of each company.

The joint venture must be supported by an agreement duly notarized (see suggested model in Form C: Joint Venture Agreement) which must:

- Indicate the name of the joint venture;
- Indicate that all members will be jointly and severally liable for the fulfillment of any contract resulting from the process;
- One of the members of the joint venture must be the manufacturer, company for which the device is manufactured ("manufactured for"), importer or holder, and must be registered and indicated in the sanitary registration as indicated in numeral 2.4;
- Designate one of the members as the leader, who must be a manufacturer of at least one of the products offered. This member shall be designated to receive payments;

- Designate the legal representative leader of the consortium as the representative of the joint operation to sign the bid and the contract;
- Indicate that the term of the joint venture shall be for at least two (2) years from the day following the deadline for submission of bids in the General tab of the eSourcing system;
- Indicate the lots for which you participate as a joint venture;
- To be signed by each of the legal representatives of the members of the joint operation;
- Indicate the percentage of participation of each of the members and their responsibilities in accordance with Form D: General information of the joint venture;
- Be duly notarized before a notary public.

With regard to the leader of the joint operation, he/she shall:

- Be the signatory to the contract, therefore it must have the authority to make binding decisions on behalf of the joint venture during the process to incur obligations and receive instructions for and on behalf of each and every member of the joint venture as well as the execution of the entire contract, including payments;
- Be responsible for bid submission on behalf of the joint venture through the eSourcing system;
- Submit bid security on behalf of the consortium, the security must be in the name of the lead member of the joint venture;
- Act as a point of contact for communications with UNOPS.

It is acceptable for a member of the joint venture to bid individually for one or more lots if it does not compete with:

i. The joint operation in which it is an integral part of the same lot, and;

ii. Another member of the joint operation on the same lot.

1.5. Apostille of documentation

UNOPS reserves the right to request from any bidder the certification of the documentation submitted in simple copy, and the legalization as total or partial apostille of the documentation issued and/or signed or certified by foreign authorities at any time during the process prior to the signing of the contract, or as a condition for the subscription of this contract.

1.6. Language of the bid

In accordance with Article 28 of Section I: Instructions to Bidders, documents submitted in a language other than English or Spanish must be submitted with a certified translation into English or Spanish.

Although the language of the bid may be any of the languages indicated in the Tender Particulars tab in the eSourcing system; the official language of all documents issued by UNOPS under this invitation for bids shall be Spanish.

1.7. Information of the contract type

Information in reference to the contract is set forth in Section V: Contract Model.

1.8. About the price offer

Unit prices are required to be quoted to **two (2) decimal digits**.

In the case of bids with more digits than those indicated, the unit prices shall be rounded to the number of decimal digits indicated according to the currency of the bid. The rounded unit prices shall constitute the unit prices of the bid for all purposes of this process as well as of the resulting contract(s).

The total amounts per lot will be expressed to two (2) decimal digits, by rounding at the time of calculating the total amount of each lot.

2. Criteria

2.1. Formal and eligibility criteria (preliminary evaluation)

The criteria to be evaluated under the acceptance/rejection condition are listed below.

All bidders must comply with the criteria listed below unless explicitly stated otherwise.

Criteria
1. The bidder complies with the eligibility conditions indicated in Section I, Article 4 of this document.
1.1. The bidder is a private, public or government-owned legal entity, or any association that has the legal capacity to enter into a binding contract with UNOPS. In case of a joint venture, each partner must meet this criterion.
1.2. The bidder does not have any conflict of interest to participate and must disclose any actual or potential conflict of interest in the Bidder/Partner Information Form for a joint venture (Form E). In the case of a joint venture, each member must meet the criterion by completing the corresponding Form E.
1.3. The bidder is not, at the time of submitting the bid or during any stage of the evaluation process, on the ineligibility lists indicated in Article 4 of Section I of this document. UNOPS will verify the ineligibility lists and in addition the bidder must submit the Affidavit included in Form E. In the case of a joint venture, each member must meet the criteria.
1.4. The bidder adheres to the principles of the United Nations Supplier Code of Conduct and the principles of the United Nations Global Compact by filling out Form B. In the case of a joint venture, each member shall comply with the criteria. To do so, you must declare compliance in the Cuestionario Operaciones Conjuntas Declaración Cumplimiento de Código de Conducta de proveedores de Naciones Unidas available in the eSourcing Questionnaires tab.
2. The bidder accepts the terms of the contract and confirms the validity of its bid.
2.1. The bidder accepts the general and special conditions of contract and confirms the validity of its bid as required in the eSourcing Details tab, having declared this in the bid cover letter (Form A: Submission of Bid). In case of a joint venture, only one form applies for the joint venture.
2.2. The person signing the bid has authorization, which must be demonstrated by submitting the power of attorney granted to the signatory of the bid and the personal identification document of the Legal Representative or Mandatory. In case the person is a non-Mexican national, a copy of the biographical page of the passport must be submitted. In case of joint operation, the joint operation agreement must be included.
3. The Manifest/bid security is in compliance with the eSourcing system Details tab.
3.1. Conforms to the corresponding format [Bid Support Manifest (Form B, Option 1) or Bid Security (Form B: Option 2)], according to the conditions indicated.
3.2. It complies with the required validity.
3.3. In the case of Bid Security, the United Nations Office for Project Services (UNOPS) is designated as the beneficiary.
3.4. In the case of a Bid Security, it is issued by an entity acceptable to UNOPS.

3.5. In the case of a Bid Security, it is in the same currency of the bid and with the required amount.

2.2. Qualification Criteria (Prequalification)

The criteria to be evaluated under the acceptance/rejection condition are listed below.

Criteria
1. Legal constitution of the bidder, seniority and commercial line of business.
1.1. The bidder is currently prequalified for which they must submit the Notification of Prequalification letter in any of the bidding processes conducted by UNOPS for the December 2020 procurement of drugs and/or medical supplies (ITB/2020/17938, ITB/2020/17978, ITB/2020/17979, ITB/2020/18035 and/or ITB/2020/18036). Prequalified bidders may complete Form C: Prequalified Bidder Information in which they may submit documentation that has been modified since prequalification was received. UNOPS reserves the right to request any additional information resulting from the review of the changes indicated.
1.2. The bidder has been legally constituted for at least three (3) years as of the deadline for submission of bids and the business line of the bidder is related to the purpose of this process. Prequalified bidders are not required to submit this documentation again. If it has been modified since prequalification, Form C should be used to update the information/documentation. In the case of a non-prequalified joint venture, this criterion applies to all members of the joint venture.
2. The bidder provides the required information on Forms D and/or E.
2.1. Bidder provides the complete information required in Form D: Joint Venture General Information. Applicable to joint ventures only.
2.2. The bidder provides the complete information required on Form E . In the case of individual bidders, only Form E.1: Individual Bidder or Leader (Member 1) of a joint venture information is required to be completed. In the case of pre-qualified bidders, each member is required to complete a Form E. Form E.1: Individual or Lead Bidder (Member 1) Information for a joint venture is to be completed by the lead member. The remaining forms (E.2, E.3, E.4 and E.5) should be completed by the other members of the joint venture, using one form for each member.
3. Legalized joint operation agreement. Applicable only to joint operations. In the case of a prequalified joint venture, the agreement must comply with the required term, and the bidder must submit the amendment to the agreement using Form C: Prequalified Bidder Information.
3.1 Includes the name of the joint operation.
3.2. It states that all members are jointly and severally liable for the fulfillment of the contract.
3.3. It is duly notarized or by a public broker duly authorized by the Public Brokerage of the Government of Mexico.
3.4. Designate one of the members as leader.
3.5. The member designated as leader of the joint operation complies with the conditions established in this document.
3.6. Appoints the legal representative of the lead member as representative of the joint operation to sign the bid and contract.
3.7. It is valid for at least two (2) years from the day following the deadline for submission of bids.
3.8. Indicates the lots for which the joint operation is bidding.

3.9. It is signed by each of the legal representatives of the members of the joint venture.
3.10. Detail the percentage of participation of each of the members as well as the responsibilities of the same in congruence with the information provided in Form D: General information of the joint operation.
4. Bidder's experience in contracts for similar goods.
4.1 The bidder has experience in the satisfactory execution of contracts for similar[1] goods, in the last three (3) years, the amount of which is greater than MXN 1,500,000.00 or its equivalent in USD at the United Nations[2] exchange rate in effect at the deadline for submission of bids. Bidders must complete Form F: Bidder's Experience and for each experience submit invoices, final receipt certificate, delivery note, or its equivalent. In the case of a joint venture, the experience of each member shall be cumulative to meet this criterion. Prequalified bidders should not submit this documentation again. If the documentation has been modified since prequalification, Form C must be used to update the information/documentation.
5. Liquidity Ratio
5.1. The liquidity ratio[3] is equal to, or greater than, 0.75, for which the bidder must submit the Financial Statements for the last two (2) immediately preceding fiscal years (2020 and 2019) certified by a Certified Public Accountant or equivalent, as well as the valid Certified Public Accountant's Certification (or equivalent), issued by an entity that endorses the public accountant to exercise his/her functions in the country of origin. In the case of a joint venture, the liquidity ratio for each year shall be calculated as the sum of the current assets of all the members of the joint venture divided by the sum of their current liabilities. Prequalified bidders are not required to provide this documentation. However, the bidder may submit with its bid financial statements using Form C: Prequalified Bidder Information for Financial Capacity Calculation Purposes, as indicated in Article 2.7. Financial Capacity.
6. Supplier commitment to sustainability
6.1. The bidder shall demonstrate its commitment to incorporate sustainability into its own operations (in accordance with social, environmental and economic considerations). The bidder shall comply with the following points: 1. Complete the Bidder's Sustainability DRIVE Questionnaire, as well as the Sustainability Practices Information Form and submit them as part of its bid. 2. Submit the completed Sustainability Practices Information Form as part of your bid; 3. Provide at least one (1) of the following documents: a. Expired Supplies Return Plan: General plan for removal of expired products from delivery points for proper disposal; b. Accessibility: Document detailing the inclusion of Braille labels on packaging, labeling or instructions to ensure easy handling and use by visually impaired persons; c. Environmental Management System: Documentation confirming that the manufacturers producing the drugs have valid ISO-14001 EMS[4], EMAS[5] or similar certification. Applicable to all individual bidders or joint ventures, prequalified or not. With regard to items 1 and 2, in the case of a joint venture, the lead member must comply with the aforementioned criteria, UNOPS reserves the right to request the questionnaire/form from the other members of the joint venture at a later date.
7. Gender Equality

[1] The term "similar" shall be understood to mean drugs, medical supplies or healing materials.

[2] Available at https://treasury.un.org/operationalrates/OperationalRates.php.

[3] Liquidity ratio = Current assets / current liabilities.

[4] Environmental Management Systems (EMS).

[5] EU Eco-Management and Audit Scheme (EMAS).

7.1. Gender Mainstreaming in Contract Execution Following the UNOPS Gender Parity Strategy and Gender Equity Strategy in line with the UN System Gender Equality Strategies, the bidder must complete the self-assessment using the WEP tool (available at https://weps-gapanalysis.org) to understand its contribution to advancing gender equality and gender parity and attach the outcomes with its bid. Applicable to all individual bidders or joint ventures, prequalified or not.

2.3. Administrative Criteria

2.3.1. Tie/Draw resolution

In the event of a tie, UNOPS may use at its discretion - without prejudice to any action it takes to ensure non-collusion among bidders - the "Best and Final Offer" (BAFO) methodology to identify the lowest priced bid for lots with a price tie. To this end, bidders will be notified in writing and requested to submit their Best and Final Offer for the affected lot.

Bidders may not change the specifications of the product offered or any of the conditions of the bid (delivery times, terms, special conditions, etc.) and only the unit price may be changed.

Subsequently, a new price comparison will be made on the affected lot. If a tie persists, UNOPS reserves the right to re-solicit a BAFO or reject bids for that lot.

2.3.2. Qualifying Administrative Criteria

The criteria per lot (key) to be evaluated under the acceptance/rejection criteria are listed below.

No.	Criteria	Source for Verification
1	The offer is for the total required quantities for the second half of 2022 to be procured via a Purchase Order.	Form H: technical offer per lot
2	The bid undertakes to comply with the conditions indicated in paragraph 4.D. Scheduling of deliveries in Section VI: Contract Management.	Form H: technical offer per lot

2.4. Qualifying Technical Criteria

Listed below are the criteria to be evaluated under the acceptance/rejection condition for each lot (key) according to the following scenarios:

- The medical product/device has a Sanitary Registration issued by COFEPRIS.
- Medical product/device of foreign manufacture WITHOUT Sanitary Registration issued by COFEPRIS that have Sanitary Registration or Commercialization Authorization issued by Regulatory Agencies with equivalence recognition.
- Products that are not considered a Health Supply and that are listed in Annex 2 of the DOF of 12/22/2014.

2.4.1. The medical product/device WITH a Sanitary Registration issued by COFEPRIS

No.	Criteria	Evaluation of the Criterion
1	The medical product/device has commercialization approval.	Valid Sanitary Registration issued by COFEPRIS. In case the Sanitary Registration is expired or is awaiting approval for extension, it is required to submit additionally the application for extension of the Sanitary Registration, indicating the entry number of the process and product name for the lot(s) offered. The request for extension must have been filed with COFEPRIS at least 150 calendar days before the date on which the term of the sanitary registration expires. When the last day of the deadline for the presentation of the extension is a non-business day, it will be understood to be extended until the following business day. In any case, requests for late extensions will be accepted when modifications,

		suspensions of terms or extensions of the deadline for submitting extensions are published in the Official Journal of the Federation, and the bidder must attach such publication.
2	The bidder is registered and indicated in the Sanitary/Health Registration, or Commercialization Authorization.	The bidder (in case of a joint venture, one of the members) must appear as manufacturer, company for which the device is manufactured ("manufactured for"), importer or holder, and must be registered and indicated in the sanitary registration. Additionally, if the bidder submitting the bid is the manufacturer, the company for which it is manufactured or the importer registered in the Sanitary Registration, it must submit Form D: Authorization of the holder registered in the Sanitary Registration.
3	The bidder complies with the technical conditions set forth in Form G: Statement of Technical Compliance of the medical product and/or device.	The bidder must submit Form G: Declaration of Technical Compliance of the medical product and/or device, duly completed with the confirmation of acceptance of the established technical criteria.
4	The bidder complies with the technical conditions set forth in Form H: Technical bid per lot.	The bidder must submit Form H: Technical Bid per Lot, duly completed with the confirmation of acceptance of the technical criteria established and the complete documentation required.

2.4.2. Medical product/device of foreign manufacture WITHOUT Sanitary Registration issued by COFEPRIS that have Sanitary Registration or Commercialization Authorization issued by Regulatory Agencies with equivalence recognition.

No.	Criteria	Evaluation of the Criterion
1	The product/device has commercialization approval.	Current Sanitary Registration, Commercialization Authorization[6] or equivalent document, issued by any of the Regulatory Agencies with equivalence recognition described below: i) Pharmaceuticals and Medical Devices Agency of Japan or, ii) the Food and Drug Administration of the United States of America or, iii) Health Canada. In the case of keys (lots) whose description includes more than one medical product-device that requires sanitary registration in Mexico, the bidder must submit the current Sanitary Registration/Commercialization Authorization for each item described in the key issued by the equivalence recognition agencies indicated in the first paragraph, if there is not a single Sanitary Registration or Commercialization Authorization that includes all the medical products or devices included in the key (lot); in these cases, in accordance with Mexican regulations, the bidder must request a Sanitary Registration from COFEPRIS that includes all the components of the key. In case the Sanitary Registration, Commercialization Authorization or equivalent document is expired or pending approval of extension by the Regulatory Agency with equivalence recognition, the extension request must be submitted additionally indicating the number and date of entry of the process and name of the product for the lot(s) offered. The request for extension must have been submitted to the Regulatory Agency with recognition of equivalence, before the date on which the validity of the

[6] A Commercialization Authorization is an official document issued by the competent Regulatory Authority to commercialize or distribute a product in accordance with the regulatory and legal framework in force.

		sanitary registration or commercialization authorization expires and in accordance with the time periods established within the Regulatory Agency's own regulatory framework.
2	The bidder is registered and indicated in the Sanitary Registration or Commercialization Authorization.	The bidder (in case of a joint venture, one of the members) must appear as manufacturer, company for which the device is manufactured ("manufactured for"), importer or holder, and must be registered and indicated in the sanitary registration that will be issued by COFEPRIS; for which it must fill in the corresponding fields of Form G: Statement of Technical compliance of the product and/or medical device. Additionally, if the bidder submitting the bid is the manufacturer, the company for which it is manufactured or the importer that will be registered in the sanitary registry issued by COFEPRIS, it must submit Form D: Authorization of the holder registered in the sanitary registration.
3	The bidder complies with the technical conditions set forth in Form G: Statement of Technical Compliance of the product and/or medical device.	The bidder must submit Form G: Statement of Technical Compliance of the product and/or medical device, duly completed with the confirmation of acceptance of the established technical criteria.
4	The bidder complies with the technical conditions set forth in Form H: Technical bid by lot.	The bidder must submit Form H: Technical Bid per Lot, duly completed with the confirmation of acceptance of the technical criteria established and the complete documentation required.

2.4.3. Supplies/Products that are not considered a Health Supply and that are listed in Annex 2 of the DOF of 12/22/2014

No.	Criteria	Evaluation of the Criterion
1	The device/product of Domestic or Foreign Manufacture listed in Annex 2 of the DOF of 12/22/2014 has commercialization approval.	An affidavit issued by the bidder stating that the product is listed in the reference DOF, indicating the DOF page and item number of the product offered, will be accepted.
2	Authorization by the manufacturer	When the bidder submitting the bid is not the manufacturer of the product offered, it must submit Form F: Manufacturer's Authorization.
3	The bidder complies with the technical conditions set forth in Form G: Statement of Technical Compliance of the product and/or medical device.	The bidder must submit Form G: Statement of Technical Compliance of the product and/or medical device, duly completed with the confirmation of acceptance of the established technical criteria.
4	The bidder complies with the technical conditions set forth in Form H: Technical	The bidder must submit Form H: Technical Bid per Lot, duly completed with the confirmation of acceptance of the technical criteria established and the complete documentation required.

	bid per lot.	

2.5. Complementary Technical Criteria

According to the risk classifications for the products and medical devices to be evaluated in this ITB, the definitions [7]of each of them are detailed below:

- Low risk: Those medical equipment, prosthetics, orthotics, functional aids, diagnostic agents, dental supplies, surgical and healing materials and hygienic products known in medical practice, whose safety and efficacy is duly proven and supported by various means of technical and scientific information, for which the Federal Commission for the Protection against Health Risks has performed the corresponding risk assessment, classifying them as low risk, which are detailed in Annex 1 of the DOF of 12/31/2011.[8]
- Class I: Those products known in medical practice and whose safety and efficacy are proven and, generally, are not introduced into the organism.
- Class II: Those products known in medical practice and which may have variations in the material with which they are manufactured or in their concentration and, generally, are introduced into the organism and remain in the body for less than thirty days.
- Class III: Those products that are new or recently accepted in medical practice, or that are introduced into the organism and remain in it for more than thirty days.
    - Active implantable Class III medical devices: An implantable medical device is any product designed to be totally implanted in the human body, or to replace an epithelial surface or the ocular surface by means of surgical intervention and intended to remain there after the intervention. An implantable product is also considered to be any product intended to be partially introduced into the human body by surgical intervention and to remain there after such intervention for a period of at least thirty days. An active medical device is a device whose functioning depends on a source of electrical energy or any source of energy other than that generated directly by the human body or by gravity, and which acts by conversion of such energy.
- They are not health products: those products that due to their nature, characteristics and use are not considered as health products and therefore do not require sanitary registration, which are detailed in Annex 2 of the DOF of 12/22/2014.

The following is a list of the criteria to be evaluated under the acceptance/rejection condition for each lot offered, according to the following scenarios:

- Products or Medical Devices Low Risk, Class I, II and III
- Supplies/products that are not considered a Health Input that are listed in Annex 2 of the DOF of 12/22/2014.

2.5.1. Products or Medical Devices Low Risk, Class I, II and III

No.	Criteria	Evaluation of the criterion for products WITH Sanitary Registration issued by COFEPRIS	Evaluation of the criterion products WITHOUT Sanitary Registration issued by COFEPRIS that have Sanitary Registration issued by Regulatory Agencies with equivalence recognition.
1	Manufacturer has Good Manufacturing Practices or	National Manufacture: Submit current Good Manufacturing Practices (GMP) Certificate issued by	Present a valid Certificate of Good Manufacturing Practices, in the name of the manufacturer of the

[7] Definition of risk classification according to the Regulation of health products, LAST REFORM PUBLISHED IN THE OFFICIAL JOURNAL OF THE FEDERATION: MAY 31, 2021. Article 83

[8] Listed in annex 1 of the DOF of 12/31/2011

No.	Criteria	Evaluation of the criterion for products WITH Sanitary Registration issued by COFEPRIS	Evaluation of the criterion products WITHOUT Sanitary Registration issued by COFEPRIS that have Sanitary Registration issued by Regulatory Agencies with equivalence recognition.
	equivalent Quality [9] Certificate	Cofepris. The certificate must correspond to the establishment(s) authorized in the Sanitary Registration or Commercialization Authorization submitted and where the product is manufactured. Good Manufacturing Practices Certificates must include the production line for the manufacture of the medical product/device. If the Good Manufacturing Practices certificate has expired or is awaiting a visit for renewal, an additional document certifying the request for renewal of the certificate prior to its expiration must be submitted. Renewals of Good Manufacturing Practices Certificates issued by COFEPRIS must have been submitted 180 calendar days prior to the date on which the certificate expires. When the last day of the deadline for the renewal request is a non-business day, it will be understood to be extended until the following business day. Applications for renewal of the certificate will only be accepted extemporaneously when suspensions of terms or extensions of the deadline are published in the Official Gazette of the Federation, for which the bidder must attach such publication. Foreign Manufacture: In case the medical product/device is of foreign manufacture submit any of the following documents: ● Certificate of Good Manufacturing Practices issued by the Health Authority or by the corresponding Ministry that regulates the product, including COFEPRIS. ● ISO 13485 certificate, current version, issued by an authorized organization. ● CE marking certificate for medical devices issued by an authorized organization in the	product/medical device, issued by the health authority or one of the equivalent documents indicated below: ● Certificate of Good Manufacturing Practices issued by the Health Authority or by the corresponding Ministry that regulates the product. ● ISO 13485 certificate, current version, issued by an authorized organization. ● CE marking certificate for medical devices issued by an authorized organization in the European Union. ● Declaration of compliance with Good Manufacturing Practices included in the Certificate of Free Sale issued by the Health Authority or, if applicable, by the corresponding Ministry that regulates the product. ● Latest EIR- Establishment Inspection Report (clase I FDA and class II with 510k) issued by FDA o MDSAP- Medical Device Single Audit Program ● Medical device with Sanitary Registration from HC - Health Canada: ISO 13485, ISO 17021 and certified copy of the current authorization issued by HC to the authorized third party that issued the ISO certificate. Details of the Certificate of Good Manufacturing Practices to be presented, or its equivalent documents. ● The document must endorse the manufacturing line of the medical device (or the device). ● If the document is in a language other than English or Spanish, attach a simple translation. ● If the document is not valid,

[9] Guide on the application of criteria to be observed for the evaluation of the certification of good manufacturing practices for drugs, medicines, medical devices and primary packaging warehouses accompanying applications for modifications, extensions and sanitary registrations. COFEPRIS, March 2020

No.	Criteria	Evaluation of the criterion for products WITH Sanitary Registration issued by COFEPRIS	Evaluation of the criterion products WITHOUT Sanitary Registration issued by COFEPRIS that have Sanitary Registration issued by Regulatory Agencies with equivalence recognition.
		European Union. • Declaration of compliance with Good Manufacturing Practices included in the Certificate of Free Sale issued by the Health Authority or, if applicable, by the corresponding Ministry that regulates the product. • Latest EIR- Establishment Inspection Report (clase I FDA and class II with 510k) issued by FDA o MDSAP- Medical Device Single Audit Program • Medical device with Sanitary Registration from HC - Health Canada: ISO 13485, ISO 17021 and certified copy of the current authorization issued by HC to the authorized third party that issued the ISO certificate. The document submitted must endorse the manufacturing line of the medical device (or the device). If the document is in a language other than English or Spanish, attach a simple translation. If the document is not valid, attach the proof of the renewal request submitted to the corresponding authority. Renewals of Good Manufacturing Practices Certificates issued by Regulatory Agencies with recognition of equivalence must be submitted within the time limits established in the regulatory framework of the Regulatory Agency issuing the submitted Certificate. If the validity of the document is not stated, the issuance of the document must not exceed 30 months. Requests for renewal of the certificate or equivalent document will only be accepted extemporaneously when the Health Authority or the corresponding Ministry that regulates the product publishes suspensions of terms or extensions of the deadline, for which the bidder must attach such publication. In the event that the offered product is classified as low risk according to Annex 1 of the DOF of 12/31/2011, instead of the GMP, it may present a notice of operation in force for health inputs	attach the proof of the renewal request submitted to the corresponding authority. Renewals of Good Manufacturing Practices Certificates issued by Regulatory Agencies with recognition of equivalence must be submitted within the time limits established in the regulatory framework of the Regulatory Agency issuing the submitted Certificate. • If the validity of the document is not stated, the issuance of the document must not exceed 30 months. Requests for renewal of the certificate or equivalent document will only be accepted extemporaneously when the Health Authority or the corresponding Ministry that regulates the product publishes suspensions of terms or extensions of the deadline, for which the bidder must attach such publication. In the event that the offered product is classified as low risk according to Annex 1 of the DOF of 12/31/2011, instead of the GMP, it may present a notice of operation in force for health inputs issued by Cofepris, the Mexican health authority.

No.	Criteria	Evaluation of the criterion for products WITH Sanitary Registration issued by COFEPRIS	Evaluation of the criterion products WITHOUT Sanitary Registration issued by COFEPRIS that have Sanitary Registration issued by Regulatory Agencies with equivalence recognition.
		issued by Cofepris, the Mexican health authority.	
2	The product-device complies with the labeling approved by the corresponding Regulatory Agency	Photograph or final model of the labeling of the primary and secondary container or, the final labels of the primary and secondary containers approved by COFEPRIS.	Photograph or model of the label design of the primary and secondary containers approved by the Regulatory Agency with Recognition Agreement, if it is in a language other than English or Spanish, accompanied with a simple translation.
3	The medical device complies with the offered quality criteria	Analytical certificate of the medical product-device (last batch manufactured and not older than five years), showing compliance with the acceptance parameters established according to the type of product, including the sterility test for those supplies and / or sterile medical devices, in order to guarantee its safety, efficacy, quality and functionality; indicating the analysis methodology, pharmacopoeia or technical standards of reference and version. In case the product has not been manufactured/commercialized, attach the analytical certificate of the pilot batches.	Analytical certificate of the medical product-device (last batch manufactured and not older than five years), showing compliance with the acceptance parameters established according to the type of product, including the sterility test for those supplies and / or sterile medical devices, in order to guarantee its safety, efficacy, quality and functionality; indicating the analysis methodology, pharmacopoeia or technical standards of reference and version. In case the product has not been manufactured/commercialized, attach the analytical certificate of the pilot batches.
4	Medical devices meet intended purpose, use and precautions.	Instructions for use or operation manual or leaflet or insert containing information on the use, precautions and characteristics of the medical device offered.	Instructions for use or operation manual or leaflet or insert containing information on the use, precautions and characteristics of the medical device offered.
5	The medical product-device has technical support documents.	Updated technical data sheet (not older than 5 years), which allows verifying all the technical specifications of the product/medical device offered. The data sheet must contain at least a description of the essential properties and characteristics of the product, use, composition, materials, measurements, presentation, packaging, functioning, sterilization, if applicable.	Updated technical data sheet (not older than 5 years), which allows verifying all the technical specifications of the product/medical device offered. The data sheet must contain at least a description of the essential properties and characteristics of the product, use, composition, materials, measurements, presentation, packaging, functioning, sterilization, if applicable.
6	Correspondence of the offered product with the requirement.	The description of the key according to Section III: List of Requirements, will be validated in the documents submitted with the bid. When the description of a lot allows more than one option regarding the characteristics of the product or medical device, the bidder must demonstrate and/or declare the materials or	The description of the key according to Section III: List of Requirements, will be validated in the documents submitted with the bid. If the commercial presentation of the product listed in the sanitary registration with recognition agreement differs from that required, the bidder must obtain a sanitary registration

No.	Criteria	Evaluation of the criterion for products WITH Sanitary Registration issued by COFEPRIS	Evaluation of the criterion products WITHOUT Sanitary Registration issued by COFEPRIS that have Sanitary Registration issued by Regulatory Agencies with equivalence recognition.
		composition of the product offered in the sanitary registration and/or labels and/or technical data sheet. In case the bidder is offering more than one material or composition option, all of them must be demonstrated and/or declared. The bidder must submit high-resolution images of each of the products, which must match exactly what is offered and clearly show the product, primary and secondary packaging material. The images submitted must clearly identify the parts and characteristics of the product offered, additionally it is requested to submit within the photographs/images a graphic scale that allows to dimension the product.	issued by COFEPRIS that includes the required commercial presentation. When the description of a lot allows more than one option regarding the characteristics of the product or medical device, the bidder must demonstrate and/or declare the materials or composition of the product offered in the sanitary registration and/or labels and/or technical data sheet. In case the bidder is offering more than one material or composition option, all of them must be demonstrated and/or declared. The bidder must submit high-resolution images of each of the products, which must match exactly what is offered and clearly show the product, primary and secondary packaging material. The images submitted must clearly identify the parts and characteristics of the product offered, additionally it is requested to submit within the photographs/images a graphic scale that allows to dimension the product.
7	Proof of initiation of the Sanitary Registration application process before COFEPRIS.	Not applicable.	The Proof of application for sanitary registration must be submitted to COFEPRIS within a term not to exceed ten (10) business days, once it is requested by UNOPS through a request for clarification in the eSourcing system, during the evaluation stage of complementary technical criteria. The bidder (in case of joint venture, one of the members), must appear as the manufacturer, company for which the device is manufactured, importer or holder, and must be registered and indicated in the health registration process before COFEPRIS. The product or medical device to be registered must correspond to the description of the key according to Section III: List of requirements. The Sanitary Registration issued by COFEPRIS will not be required for the evaluation, however, it is a condition for the execution of the contract as indicated in Section VI. Contractual Management, numeral 3.4 Documents to be submitted for the issuance of the

No.	Criteria	Evaluation of the criterion for products WITH Sanitary Registration issued by COFEPRIS	Evaluation of the criterion products WITHOUT Sanitary Registration issued by COFEPRIS that have Sanitary Registration issued by Regulatory Agencies with equivalence recognition.
			Purchase Order.
8	Have a duly authorised manufacturing license	Have a duly authorised manufacturing license (operation notice for national manufacturers), valid for all relevant manufacturing sites and activities performed, issued by theNational Regulatory Authority of the country of manufacturing.	Have a duly authorised manufacturing license, valid for all relevant manufacturing sites and activities performed, issued by theNational Regulatory Authority of the country of manufacturing.
9	Valid and certified Quality Management System (QMS) certificate	Have a valid and certified Quality Management System, according to the following requirements: a. latest versions in force ISO 13485 or ISO 9001, when the first is not applicable, or an equivalent Quality Management System standard (equivalence defined below from b. to c.); b. the Quality Management System shall include the scope and the locations and facilities where the relevant activities are performed; c. the Quality Management System shall be issued by the Conformity Assessment Body, Notified or Accredited bodies recognised by the Regulatory Authority of one of the GHTF (Global Harmonization Task Force) Founding Member countries and shall be recognised by such Authorities. Manufacturers of sterile products shall also have a valid and certified Quality Management System, according to the previous point, covering the sterilisation plants and processes. This critera applies to class I, II and III products; in the case of products classified as Low Risk, the submission of the certificate will be optional.	

2.5.2. Supplies/products that are not considered a Health Product listed in Annex 2 of the DOF of 12/22/2014

No.	Criteria	Evaluation of the Criterion
1	~~The product has a Notice of Operation.~~ Have a duly authorised manufacturing license	~~Valid Notice of Operation of health products issued by COFEPRIS in Mexico.~~ ~~The document must include: Company name, address, authorized classification, manufacturing lines of the medical device, sanitary responsible, date of issue and signature.~~ Have a duly authorised manufacturing license (operation notice for national manufacturers), valid for all relevant manufacturing sites and activities performed, issued by theNational Regulatory Authority of the country of manufacturing.
2	The product-device complies with the labeling approved by the corresponding regulatory agency.	Photograph or final model of the labeling of the primary and secondary packaging.
3	The medical product-device has technical support documents.	Updated technical data sheet of the product not older than 5 years that allows verifying all the technical specifications of the product/product offered. The data sheet must contain at least a description of the essential properties and characteristics of the product, use, composition, materials, measurements, presentation,

		packaging, forms, structure, functioning, sterilization, if applicable.
4	Correspondence of the offered product with the requirement.	The description of the key according to Section III: List of Requirements, will be validated in the documents submitted with the offer. The description of the product offered shall correspond with the description in Annex 2 of the DOF of 22/12/2014 and the National Compendium of Health Inputs. During bid evaluation, UNOPS reserves the right to require high resolution images of any of the products offered. The images must match exactly what is offered and clearly show the product, primary and secondary packaging material and artwork.

2.6. Price Evaluation

The bids with the lowest price per lot that have passed the evaluation of the supplementary technical criteria will be submitted to:

2.6.1. Analysis of bid price reasonableness

UNOPS will verify that the price corresponds to a reasonable price in accordance with the regulations and procedures to which UNOPS is subject.

A reasonable price is understood to be that which, after a comparison analysis with local historical prices, valid bid prices and, if applicable, international purchasing prices, for the drug in the same commercial presentation and unit of measure required, is considered reasonable in relation to market conditions in order to guarantee the best quality to price ratio. In the event that the price is not reasonable in the opinion of UNOPS, UNOPS may seek to negotiate the bid price or reject the bid.

2.6.2. Negotiation

UNOPS reserves the right to invite the lowest substantially compliant bidder to negotiate for one or more lots when its bid price is considered unreasonable or when it is a candidate for the award of multiple lots, in which case UNOPS will notify the bidder in writing of its intention to negotiate and instructions as to how the negotiation will be conducted.

Following the negotiation, UNOPS will verify the reasonableness of the negotiated bid price, which does not imply an award.

2.7. Financial Capacity

For prequalified bidders, the Financial Capacity shall be calculated using the documentation previously submitted. However, the bidder may submit with its bid updated financial statements using Form C: Prequalified Bidder Information.

To determine the financial capacity of a bidder, the following procedure shall be applied:

- Financial capacity limit [A]: The sum of sales for the last two (2) fiscal years. In the case of bidders in a joint operation, the financial capacity limit will be calculated on the basis of the sum of the capacities of their members. The financial capacity of the bidders' subcontractors will not be taken into account;
- Estimated Amount to be Awarded [B]: Sum of all lot amounts for which the bidder is the lowest technically qualified bidder; corresponding to the quantities for the second semester of 2022;
- Bids in other processes [C]: In cases where the bidder participates in several bidding processes executed by UNOPS at the same time, the awards already made in those processes will be taken into account;
- Balance of contracts in execution [D]: Sum of the balances as of the date of the bid opening for contracts signed with UNOPS;

- Total amount [E]: Total resulting from the sum of all values [B] for the bidder in the process plus bids in other processes [C], and the balances of contracts under execution [D].

If the Bidder's Financial Capacity Limit [A] is less than the Total Amount [E], i.e. if A < E, UNOPS reserves the right to determine the lots to be awarded in a manner most favorable to UNOPS, including the following options, but not limited to:

- In the case of prequalified bidders, request the most recent Financial Statements;
- Partially award one or more lots (keys) within the UNOPS variation right according to clause 1.3 of this section;
- Award one or more lots to another bidder whose price is reasonable and who has the financial capacity;
- If there are no other qualified offers, one or more lots may be rejected in order to obtain the most favorable configuration for UNOPS.

If required, currency conversion will be made using the United Nations exchange rates in effect at the deadline for submission of bids.