Section III: List of Requirements

1. Technical Specifications, Quantities, and Delivery Plan/Schedule

To know the products or medical devices required in this invitation to bid, please refer to document IM_0301ES_v020 Requerimiento por lote.xlsx.

2. General Requirements

2.1. Expiration date of medical products, supplies and devices

Products must be in effect at the time of delivery as follows:

A. In general, **not less than 12 (twelve) months** from the date of receipt at the delivery points indicated in the Purchase Order by UNOPS;
B. In those products or medical devices that, due to their nature, have an expiration period of less than 12 (twelve) months, they must prove with the Sanitary Registration granted or sworn statement, that the goods have a shorter expiration date. If, for any reason, there is a shortage of the product in the market, UNOPS may accept products with a shorter expiration date than those specified above, after a prior risk analysis.

Replacement of products, supplies or medical devices with an expiration date of less than 12 months:

Exceptionally, UNOPS may authorize the delivery of products with an expiration period of less than 12 (twelve) months, but not less than 9 (nine) months counted from their arrival at the delivery points/locations indicated in the Purchase Order. On such occasions, the Supplier shall submit a replacement commitment letter, in accordance with the attached form in Appendix 1, Section VI: Contract Management, indicating the lot(s) to be delivered, the expiration date at the time of delivery, the delivery locations, and the corresponding quantities.

With each batch per product delivery, you must invariably submit a replacement letter in accordance with the attached Appendix 1 of Section VI: Contractual Management in which you agree to exchange, within 15 working days from the replacement notification, those products, supplies or medical devices that have not been consumed before their expiration date. This replacement will be at no cost to UNOPS or INSABI. The health institution must notify UNOPS/INSABI of the expiring product or medical device at least one month prior to the expiration date of the product.

In cases where the replacement commitment letter applies, the bidder shall replace products that expire or are close to expiration with products that meet all the requirements established for the awarded key and that comply with the minimum expiration period stipulated in A. above.

The replacement of products, supplies or medical devices shall be performed under the following conditions:

- Deadline: within 15 working days from UNOPS notification for product replacement;
- Place: at the same location of delivery, and;
- Cost: no cost and/or fee for UNOPS and/or INSABI.

2.2. Product Matching

The medical supplies or devices offered must ~~have certification issued by the manufacturer that the device is~~ be new, not reconstructed and that it corresponds exactly with the criteria and technical specifications associated to the corresponding group, according to its classification:

- 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.[1]

- 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.

In those keys whose descriptions state "each institution will choose the material, presentation or composition" or similar, and the bidder solely offers one of the options described in the key, UNOPS will not apply the choice by each institution and 100% of the quantity to be purchased will correspond to that offered by the bidder with the lowest substantially conforming price.

If the commercial presentation does not correspond to the one indicated in the requirement, UNOPS may accept it as long as the sterility of the product (when applicable) and the integrity of the individual packaging are guaranteed. For these cases, the supplier shall comply with the description in the CNIS, if necessary, shall adjust the requested pieces to the presentations provided as long as they guarantee the complete delivery of such quantities and the individual presentation corresponds to that described in the CNIS.

In the case of differences between the dimensions and/or measures of the products offered and what is required, UNOPS may accept them if they do not affect the functionality of the goods and if ~~they comply with one of the following considerations:~~

- They are described in the SUPPLEMENT FOR MEDICAL DEVICES - PHARMACOPOEIA OF THE UNITED MEXICAN STATES 4 Edition 2017 and its updates;
- ~~They are within the tolerances of the Certificates of Analysis of products acquired by Mexican Government institutions.~~

In the event that there are differences in the characteristics of the battery of the active implantable class III medical devices, they may be accepted as long as the functionality of the product is not affected and complies with the requirements of the description of the key.

For cases in which differences to the Compendium description apply and are evaluated under the preceding paragraphs, the award will be subject to INSABI's acceptance, after review with the General Health Council.

2.3. Characteristics of materials (Packaging / Container / Labeling)

Medical products, supplies or devices must be manufactured and packaged in such a way that, under normal conditions of use, they are fit for their intended purpose. They must be safe and effective and not compromise the clinical condition or safety of patients, provided that the potential risks from their use are acceptable in relation to the benefit they provide to the patient and compatible with a high level of safety and health protection.

The contractor shall provide with each delivery per batch of product:

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

- Certificate of analysis (CoA - test report), showing compliance with the acceptance parameters established according to the type of product or medical device and its risk level, in order to guarantee its safety, efficacy, quality and functionality (use and performance). This includes sterility tests.
- Description of the analytical method of the product including pharmacopoeia and/or technical reference standards or description of own analytical methodologies if the analytical method is not pharmacopoeial.

3. Characteristics of materials (Packaging / Packaging / Labeling)

In line with United Nations measures aimed at responsible production and consumption as well as care for the environment, we encourage efforts to eliminate single-use plastics, avoid any unnecessary packaging and/or consider more sustainable alternatives such as, but not limited to, biodegradable or recycled packaging and labels, recyclable and/or reusable packaging, the take-back option, or obtaining packaging raw materials from sustainable sources, such as cardboard obtained from a sustainably managed forest that is certified to FSC, SFI, PEFC or equivalent standards. In addition, the use of sustainable inks and glues should be promoted.

3.1. Primary Packaging

Primary packaging is defined as the elements of the container-seal system whenever they are in direct contact with the product or medical device (MEXICAN OFFICIAL STANDARD NOM-137-SSA1-2008).

Packaging materials should be printed indelibly, legibly and visibly with the date of manufacture, expiration date, when applicable, serial or lot number, country of origin and storage conditions.

They must guarantee until the expiration date of the products, that:

- Products are kept in optimal packaging conditions during transportation and storage and quality, safety and efficacy are maintained;
- They are inert, isolate and protect the products or medical devices sensitive to environmental factors (light, temperature and humidity);
- The sterility of the contents is maintained if applicable;
- The information necessary for the identification, use and storage of the device, if applicable, is kept legible.

3.1.1. Sterility conditions

Packaging systems for non-sterile medical devices or products should maintain the material without deterioration at the stipulated level of cleanliness.

If the product or medical device is to be sterilized before use, the packaging system must be suitable for the sterilization method indicated by the manufacturer and guarantee the preservation of the sterile condition until use.

Medical supplies or devices delivered in a sterile state should be packaged in a non-reusable form and/or in accordance with appropriate procedures to ensure that they are sterile when they are to be used and that they remain sterile under the transport and storage conditions indicated by the manufacturer, until the protective packaging is removed or opened for proper use.

The sterilization method must be clearly indicated on the primary and secondary packaging. The bidder shall submit a copy of the sterilization certificate to UNOPS upon delivery of the product. If deemed appropriate, UNOPS may request the bidder to submit the manufacturer's standards used for sterilization validation.

3.2. Secondary Packaging

Secondary packaging is defined as the elements that are part of the packaging in which the product or medical device is marketed and that are not in direct contact with it (MEXICAN OFFICIAL STANDARD NOM-137-SSA1-2008).

Secondary containers must have printed and visible date of manufacture, expiration date, when applicable, serial or lot number, country of origin and storage conditions.

They must guarantee that the medical supplies or devices are kept in optimal packaging conditions during transportation and storage and that the quality, safety and efficacy of the product is maintained until its expiration date.

The secondary packaging must be resistant and allow the necessary protection of the primary packaging with materials that ensure the required conditions of resistance for the safe handling of the product. For example, cardboard or plastic bag type packaging will not be accepted.

All boxes must indicate the number of units that compose it, have the same number of units and clear indications for handling and storage, including the number of applications as the case may be.

3.3. Collective or Tertiary Packaging

Tertiary packaging or multiple or collective packaging is defined as any container or wrapper containing two or more primary or secondary packages (MEXICAN OFFICIAL STANDARD NOM-137-SSA1-2008).

It is the bidder's responsibility to define the stowage and the quantities contained in a tertiary container for the safety, conservation, handling and proper storage of the product. It must comply with the following specifications:

- Cardboard box or other material resistant to environmental storage conditions and that does not present incompatibility with the stowage (e.g. cardboard or paperboard packaging will not be accepted); in such a way that it facilitates handling, transport and storage, without risk of damage, sealed with tape that guarantees the integrity of the contents The packaging material of the bottles for boxes and internal subdivisions must be sufficiently resistant;
- Specify the number of primary or secondary containers contained in the tertiary packaging;
- Specify the number of boxes that can be stacked on top of each other per pallet;
- The size of the package should be congruent with the contents;
- In the case of leftovers (complements), the container containing the product must be clearly identified;
- Hermetic seal of all units.

4. Labeling and Instructions or User's Manual

4.1. General Information

A label is understood as any label, tag, mark, or graphic image that has been written, printed, stenciled, marked, embossed, debossed, stamped, engraved, adhered, or sealed on any material likely to contain the product or medical device, including the container itself.

The instruction, insert or leaflet is a document that in written or graphic form, or both, explains to the user the use or any other important information of the product or medical device and that is additional to the label or back label.

Finally, the user's manual is the document that in written or graphic form, or both, explains to the user the installation, operation, maintenance or any other important information of the medical device.

The bidder must guarantee that the products or medical devices comply with the provisions of the General Health Law, its Regulations and the MEXICAN OFFICIAL STANDARD NOM-137-SSA1-2008, in all matters related to "Labeling of medical devices", published in the Official Gazette of the Federation on December 12, 2008.

When the information is expressed in a language other than Spanish, it may be up to the same size and typographic proportionality, without opposing or contravening the text in the Spanish language. As described in NOM-137-SSA1-2008.

4.2. Labeling of primary packaging, secondary packaging, and collective packaging

The product or medical device must contain on the primary, secondary and collective packaging the legend "Property of the Health Sector" and the 10-digit code number of the product. This information may be presented by means of additional labels or text introduced by coding equipment, without covering original information.

Similarly, the following exceptions to primary packaging may be accepted:

A. Those product lots, which are already in production lines or in stock, will be accepted without the legend "Property of the Health Sector" and the 10-digit code on the primary package. The list of products that will have this condition must be submitted, referencing the production lot, once the award is initiated.

B. In case the addition of the legends "Property of the health sector" or the 10-digit code alter the safety seals or the quality of the product, they will not be included in the primary package. The list of products that will hold this condition must be submitted, referencing the production Lot, once the award is initiated.

4.3. Essential basic requirements to be taken into account for the labeling of medical products or devices.

No.	Elements of the Label	Packaging	Defines
1	Distinctive Denomination	Trademark (optional)	Primary Secondary Collective box
2	Generic Denomination	Mandatory	Primary Secondary Collective box
3	Manufacturer’s Information	Mandatory	Secondary
4	Country of Origin	Mandatory	Primary Secondary Collective box
5	Registration Number	Mandatory	Primary Secondary Collective box
6	Lot Number or Series Number	Mandatory	Primary Secondary
7	Content	Mandatory	Primary Secondary
8	Instructions of use of the medical device	Mandatory	Instructional annex or user's manual
9	Adverse incident that may cause the usage of the product	Mandatory	Instructional annex or user's manual
10	Warning or precaution legends	Mandatory	Secondary Instructional annex
11	On diagnostic equipment and agents involving radiation sources, state the legend: "Danger, radioactive material for medical use only".	Mandatory	Secondary Instructional annex or user's manual
12	Declaration of Sterility	Mandatory	Primary Secondary Collective box
13	Date of expiration, if applicable	Mandatory	Primary Secondary
14	Diagnostic agent legends	Mandatory	Primary Secondary Collective box

			Instruction annex or user's manual
15	Logo Symbols that apply	Mandatory	Primary Secondary Collective box Instruction annex or user's manual
16	Any special conditions for storage and/or handling.	Mandatory	Collective box Instruction annex or user's manual

The aforementioned is not exhaustive, therefore, the particular labeling conditions of each product or medical device are listed in NOM-137-SSA1-2008 and its applicability is subject to the provisions of such standard.

The bidder shall pack and package the goods in such a way that they preserve their original characteristics during transportation, stowage and storage.

In cases where the products or medical devices require instructions and manuals for use, they should preferably be presented in Spanish according to the labels authorized by the Federal Commission Against Sanitary Risks or with a simple translation.

5. Warranty and After-Sales Service

The bidder must submit warranty and after-sales service for class III active implantable medical devices, with the possibility of replacing the device in case of total or partial failure, without generating an additional cost for UNOPS and/or INSABI. The warranty shall be valid for at least five (5) years and shall be enforceable prior to the execution of the contract as indicated in section VI Contract Management. As acceptance to these conditions, the bidder must declare it in Form G: Declaration of Technical Compliance of the product and/or medical device.