

Certification, technical documentation and related services requirements:

OT-PS Type II post sales requirements for Medical Devices

This document details the documentation to be presented at the offer and after-sales service requirements that the goods and services provided for in this tender must meet. It is divided into two subsections:

- Section A: Regulatory requirements, technical documentation and certifications to be included with the offer:
 - A.1 Certifications to be submitted with the offer for each good offered
 - A.2 Technical documentation requirements to be submitted with the offer for each good offered
- Section B: Related service requirements.
 - Section II.1.a: Related services and documentation to be included in the offer
 - Section II.1.b: Detail of requirements for related services, activities to be carried out and documentation to be delivered by the awarded CONTRACTOR.

The goods have associated certification and documentation requirements (Section A) and related service requirements (Section B) in accordance with their complexity. **The documentation required in Sections A.1 and A.2 is mandatory and must be included in the offer.** The documentation required in tables 1 and 2 of section B, which describes the applicable requirements in case of being awarded, is NOT part of the documents to be attached with your offer.

Section A - Regulatory requirements, technical documentation and certifications to be included with the offer

This section details the requirements and technical documentation related to the requirements that the BIDDER, whether a manufacturer, distributor or local representatives, must comply with and present with the offer for each of the goods offered. Compliance with the requirements defined in this section I.1. applies to all goods subject to this process.

By submitting its offer, each bidder authorizes UNOPS to validate with the respective issuing entity that documentation presented that has been issued by competent authorities (i.e.: regulatory authorities, conformity assessment body, independent organizations, clients).

A.1 Certifications to be included with the offer

a. **Authorization of the manufacturer:** in case of not being the manufacturer of the goods offered, the BIDDER is required to attach to his offer an authorization from the manufacturer for the sale, distribution, and after-sales services of the equipment offered and to express the commitment to ensure the availability of spare parts, consumables, parts and accessories, etc. and the technical and after-sales services of the products offered for a period of 5 years from the date of delivery of the good.

b. **Marketing authorization or local health registration:** of the brands and models offered in force at the time of the offer in the country of manufacture, issued by the national regulatory authority in accordance with its local procedures.

c. **Compliance with a quality management system (QMS)** certified ISO 13485:2016 or equivalent for the manufacture of the goods offered, in force at the time of the offer. Equivalent or harmonized quality management systems (QMS) with respect to ISO 13485:2016 of local regulatory bodies of founding countries of the GHTF (United States, Canada, Japan, Australia, European Union) are valid.

The above-mentioned certificate must be issued by CAB (Conformity Assessment Body), by notified bodies or by bodies accredited by the indicated regulatory authorities, must be current and must indicate at least the following:

- Quality standard.
- Name of the certifying body.
- Country of Issue.
- Registration/certificate number
- Date of issue of the certificate.
- Certificate expiration date.

The document presented must be current, with its respective annexes where the scope of the production line related to the nature of the equipment offered is identified.

d. **Marketing authorization or recognition from regulatory agencies:** the lots offered must meet specific certification or marketing authorization requirements depending on the risk classification of the equipment. These authorizations or certificates must be issued by the regulatory authorities or authorized competent bodies of one of the following countries or regions:

- European Union: Directive (EU) 93/42/EEC or Regulation (EU) 2017/745 on Medical Devices in the European Union. Declarations of conformity apply only to class 1 devices.
- United States of America: FDA authorization for marketing in the United States of America
- Canada: SOR/98-282
- Australia: TGA Compliance Certification

- Japan: PMDA approval

The marketing authorizations must be valid at the time of submission of the offer and be applicable to the brands and models of equipment offered (these must be indicated in the certifications and/or annexes). If they expire within the next six months, The BIDDER must present a letter "commitment to deliver the new certificate before the expiration of the current certificate."

- e. **Compliance with IEC 60601-1 standard for Electrical Medical Equipment - Part 1** "General Requirements for Basic Safety and Essential Performance" (only applicable to electrical medical devices).
- f. **Specific certifications**, if indicated as part of the technical requirements.
- g. **Environmental management system:** the bidder must prove that the manufacturer it represents complies with one of the following options:
The manufacturer has an environmental management system certified under the ISO 14001 standard for the factories in which the offered equipment is produced. The above must be verified by one of the following options:
 - The factory has an Environmental Management System certified under a standard similar to the reference standard ISO 14001, bidders must provide documentation that confirms that the Environmental Management System implemented by the manufacturer meets or exceeds the reference standard. This documentation may include scientific or technical laboratory test results, technical statements/reports signed by an engineer, or other similar documentation.
 - In the event that the manufacturer is not certified, but has an Environmental Management System, the bidder must provide documentation from the manufacturer that confirms this fact, identifying how this System aligns with the Sustainable Development Goals established by the General Assembly of the United Nations.
 - In the event that the manufacturer does not have an Environmental Management System but has an Action Plan on environmental sustainability, the bidder must present documentation from the manufacturer detailing the methodology to increase the organization's sustainability measures through the presentation of a written summary of said methodology.

A.2 Technical documentation requirements to be submitted with the offer for each good offered

The BIDDER must attach with its offer ALL the necessary technical documentation that allows verification of compliance with each of the requested technical requirements. The documentation

must be the manufacturer's original version in English or French, current, refer to the brands and models offered and not be altered or modified.

UNOPS will take the necessary actions to confirm the veracity of the technical documents presented if it identifies that alterations or modifications have been made to the technical documentation; These types of actions could disqualify the offer and could eventually lead to your company being included in the list of suppliers disqualified from doing business with UNOPS.

Supporting technical documentation is considered:

- h. Catalog, technical data sheet or technical sheet of the product**, where the main characteristics and technical data of the equipment are described, in the original in the latest version prepared and published by the manufacturer, in English or French. If the catalog includes more than one product, the BIDDER must clearly indicate which catalog code number the offered product belongs to, the page where the code and/or image of the offered equipment and each of its specifications is located.
- i. User manual/Instructions for use** in French or English, preferably with pictograms. The manual must include, at a minimum, the following information:
 - Product overview and technical specifications.
 - Images and indication of the constituent parts, including accessories.
 - Operating and maintenance instructions.
 - Safety instructions.
 - Cleaning and disinfection instructions.
- j. Catalog of parts, accessories, spare parts, consumables:** the catalog must clearly indicate the reference codes or part numbers of the products offered such as: accessories, consumables and additional parts.
- a. Declaration that unpacking, assembling and start-up instructions** for each item, using pictograms and instructions in French will be provided, in case of award, prior to the signature of the contract. UNOPS reserves the right to revise the assembling instructions and to translate them in Malagasy.

Section B - Related service requirements

Related services are understood to be those services, activities or aspects that must be considered prior to and during the acquisition of a medical device to guarantee the correct delivery, installation, commissioning, safe, adequate and sustainable use of the medical equipment.

Tables 1 and 2 describe the minimum scope for each related service and cover all services and activities related to the supply, acceptance, training and maintenance of the goods during the warranty period.

The requirements for related services include details of requirements for related services, activities to be carried out and documentation. It describes the minimum scope for each related service and encompasses all services and activities related to the supply, acceptance, training, maintenance of the goods during the warranty period. Applies to the awarded CONTRACTOR. **The documentation required in this subsection is NOT part of the documentation to be submitted with the offer.**

Section B.1 Warranty and training conditions, required services and procedures

The conditions and service requirements indicated in table 1 apply to all BIDDERS who submit offers.

The CONTRACTOR will be totally and exclusively responsible for paying all costs associated with the development of related services (detailed in table 1).

Table 1. Warranty and training conditions, required services and procedures

No.	Service detail
1	Warranty. The bidder must guarantee compliance with the following conditions:
1.1	The CONTRACTOR must include, as part of the offer price, a minimum of 48-month warranty period for all products, components, and associated accessories. The CONTRACTOR must detail in the warranty certificate the works/events/actions not covered by the Warranty, that are only: errors in use that do not respect the instructions for use, intentional damage, or force majeure due to natural events.
1.2	Goods that fail during the warranty period <u>must be replaced</u> with a new good identical to the original, or with the same characteristics and specifications. Unless the CONTRACTOR proves one of the above-mentioned cases.
1.3	The warranty period will begin from the date of formal receipt of the goods at the agreed place as detailed in the purchase order.
1.4	Respond to requests for technical support, response to complaints, or requests for changes during the warranty period. The mechanism that will be used to respond to requests for technical assistance, response to complaints or requests for changes during the warranty period must be indicated, detailing the contact information and name and surname of the reference. The response must be received in no more than 16 working hours.

No.	Service detail
1.5	Ensure that all transportation, insurance and packaging costs necessary for the transportation of replacement equipment/parts/components to Madagascar during the warranty period will be covered.
1.6	The CONTRACTOR must replace the defective goods within 40 days from the request (60 days in case of furniture).
1.7	In the case of replacement of equipment under warranty, the warranty time of the replaced equipment will be equal to the warranty time originally required and will begin to count from delivery and receipt to the satisfaction of the original equipment.
2	Training
2.1	The CONTRACTOR shall provide a written and video tutorial for the unpacking, assembling and start-up instructions for each item using pictograms and in French. UNOPS reserves the right to provide to the CONTRACTOR said instructions translated into Malagasy, in this case the CONTRACTOR will include them in the packaging of each pallet and as subtitles of the video.
2.2	The CONTRACTOR shall provide a written and video tutorial for the training of the use of the goods, in French language, with instructions for use, cleaning and daily maintenance for users, common failures and how to resolve them. UNOPS reserves the right to provide to the CONTRACTOR a translation into Malagasy, in this case the CONTRACTOR will include it as subtitles of the video.
2.3	The CONTRACTOR shall provide a printed and plastified guide of the use of the goods in pictograms.
2.4	All the mentioned video tutorials shall be recorded in French language with Malagasy subtitles (when provided by UNOPS) and shall be available both as on-line tools with a correspondent QR code on the primary packaging of each item and as videos stored in an USB key included in the packaging of each kit.

Section B2. Detail of requirements for related services, activities to be carried out and documentation to be delivered by the awarded CONTRACTOR.

The CONTRACTOR will be totally and exclusively responsible for paying all costs associated with the development of related services (detailed in table 2).

Table 2. Details of related services

No.	Service detail	Documentation to be presented by the CONTRACTOR (this documentation should NOT be presented with the offer)
1	Delivery of the goods	
1.1	The CONTRACTOR must provide adequate packaging to guarantee the safety of the goods in the loading, transfer and unloading process, as specified in document "Grouping,Packaging and Labeling"	
2	Preliminary inspection	
2.1	UNOPS will inspect the packages delivered at the place of delivery, whether the port of origin or the port of destination. The quantities, integrity of the goods, and the integrity of the packaging, any sign of damage to the packaging and the goods and/or any no-compliance to the requirement will be registered and reported to the CONTRACTOR. The CONTRACTOR has the right to witness at his own cost the inspection.	
3	Assembly and commissioning	
3.1	The CONTRACTOR shall provide with the goods all tools , elements and instructions with pictograms necessary to assemble the goods.	Assembly instructions
3.2	The CONTRACTOR must present certificates of the Acceptance Tests of each equipment, carried out in the factory, in which the associated equipment can be identified and where the tests carried out and the results obtained are indicated.	Acceptance testing certificate
4	Training	
4.1	The CONTRACTOR must provide with the goods a written and video tutorial, in French language, with instructions for assembling, use, cleaning and daily maintenance for users, common failures and how to resolve them. These instructions do not replace the User manual.	Written and video tutorial
5	Final reception	

No.	Service detail	Documentation to be presented by the CONTRACTOR (this documentation should NOT be presented with the offer)
5.1	<p>The formal receipt of the goods will be carried out by the MINISTRY OF HEALTH, once, jointly UNOPS and the CONTRACTOR if he decide to participate, has verified the following:</p> <ul style="list-style-type: none"> - That the equipment, accessories, consumables and other elements detailed in the terms of reference and purchase order were delivered. - That the equipment, accessories, services and other elements are in accordance with what is offered and required according to the technical requirements included in the Bidding Document and, if not contradicting the previous ones, in the Offer. - The technical documentation as detailed in this document has been delivered. - The warranty certificate(s) have been delivered with the information required in table 1. <p>If the compliance is certified, UNOPS will accept the goods. For this purpose, a final Receipt / Certificate of Reception will be signed that confirms compliance with all the requirements above described.</p> <p>Any non conformity with the above mentioned requirements will signify the rejection of the goods. The rejected goods will not be paid and will remain for one week at disposal of the CONTRACTOR for their recollection. After one week UNOPS reserves the right to dispose of the goods at CONTRACTOR's expenses.</p> <p>The CONTRACTOR has the right to be present to the final inspection. If he fails to do so the CONTRACTOR will accept UNOPS's conclusions on the conformance of the goods to the requirements.</p>	
5.2	<p>Before final reception the CONTRACTOR must present with each one of the delivered goods, a Warranty Certificate for a minimum of 48 months, for all products, components, and associated accessories in favor of the consignee, being possible to be transferred to the beneficiaries. This must indicate the date of formal receipt from which the warranty period begins, the place of</p>	Certificate of Warranty

No.	Service detail	Documentation to be presented by the CONTRACTOR (this documentation should NOT be presented with the offer)
	<p>installation or delivery of the goods and the conditions of the warranty.</p> <p>The warranty certificate must comply with the conditions established in Section II.1.a Table 2, section 1 "Warranty".</p>	
5.3	Together with the goods the CONTRACTOR must provide User Manuals in printed and digital format at the time of delivery of the goods.	Operation manual
5.4	Together with the goods the CONTRACTOR must provide at the time of delivery of the goods a copy of the checklist(s) and/or preventive maintenance programs, with the corresponding frequency(s) recommended by the Manufacturer, and detailed instructions for preventive maintenance of the products offered. These instructions can be part of the User Manual.	Preventive maintenance program
6	Warranty-related activities	
6.1	The CONTRACTOR must include in the financial offer all costs of related services including the ones related to transportation, insurance and packaging costs necessary for replacement of goods during the warranty period.	Acceptance Commitment Letter