

Certification, technical documentation and related services requirements: OT-PS Type III 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.

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.
- k. Declaration that all related services described below will be delivered exactly as requested without any change or limitation by the Supplier in case of award.**

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.

Local technical support

If the Supplier is not a Company established in Madagascar, the Supplier shall supply post sales services through an experienced Company established in Madagascar. The local technical support Company shall count with demonstrated experience of technical support for the same or similar equipment of the offered item. The name of the *local technical support* shall be declared by the awarding company before signature of the contract. Documentation demonstrating the experience of the *local technical support* company as well as a letter of acceptance of the *local technical support* company to be responsible in solid with the Supplier of the post sales services described below shall be delivered to UNOPS before contract's signature.

Delivery

- On-site delivery and installation to the recipient institution.
- The equipment transportation from the production site to the final recipient institution shall be covered by a proper insurance paid by the supplier and issued in the name of the recipient institution.
- The supplier shall transport the equipment inside the institution to the installation site/room.

Installation

- The Supplier shall open the packages, assemble and install it according to the installation requirements.
- The supplier shall clean up the site of any packaging/shipping material after installation.
- The supplier shall make available all the consumables, measurement and calibration instruments required during commissioning operations.

Testing

- The supplier shall perform on-site testing, calibration and commissioning of the equipment and its accessories with certification of conformity to standards. After installation, testing and calibration completion, the equipment shall be operational and ready to use.
- Testing procedures will include electrical safety testing for Medical Devices.
- A complete set of commissioning forms with the entire set of tests performed and the results obtained shall be given to the beneficiary after the final installation and testing of the equipment.
- All equipment must be functioning with no physical damage and/or defect, prior to the acceptance by the end-user.

Training

- The supplier must provide trainings on the use/operation and maintenance of the equipment and all its accessories to the end-users and to the maintenance staff according to the following scheme:
 - End-user training (at least 2 hours):
 - The supplier shall train the users for the use and daily maintenance of all the equipment and software.
 - The location of the training course shall be the location where the equipment is delivered and installed. Virtual training may be accepted by the beneficiary.
 - The trainers shall be qualified experts belonging to the manufacturer and/or representatives in the country of the supplier and/or by qualified experts certified by the manufacturer. The training shall be held in French.
 - The training course for users shall focus at least on the following topics:
 - General equipment functions in the offered configuration, alarm signals and error signals showing all the possible equipment functionalities;
 - Calibrations, daily cleaning and maintenance operations in order to assure the longest equipment life;
 - Correct equipment utilization and related possible risks for users;
 - Description of all settings, parameters;
 - The training course shall be video/audio recorded and an on-line tutorial will be made available for the users.
 - Maintenance personnel training (at least 2 hours):
 - The Supplier shall train maintenance technicians made available by the beneficiary on the most frequent problems that could occur during equipment utilization and that are under the maintenance technicians' competencies.
 - The location of the training course for maintenance technicians shall be the location where the equipment is delivered and installed. Virtual training may be accepted by the beneficiary.
 - The trainers shall be qualified experts belonging to the manufacturer and/or representatives in the country of the supplier and/or by qualified experts certified by the manufacturer. The training shall be held in French.
 - The training course for maintenance technicians shall focus on at least the following topics:
 - How to assemble and disassemble the equipment;
 - General equipment functions, specific technical characteristics and alarm signals;

- Main electrical and functional schemes;
- Calibrations and daily maintenance in order to assure the longest equipment life;
- Preventive maintenance and its regular recurrence;
- Corrective maintenance (to solve the most frequent problems);
- Equipment safety use and safety controls.
- List of common spare parts needed for routine maintenance.
- The training course shall be video/audio recorded and an on-line tutorial will be made available for the users.
- The trainee will receive all the software keys that are needed for equipment maintenance (if applicable).

Warranty and maintenance

- Warranty for Three (3) years on all parts and service labor for preventive and corrective maintenance. All maintenance shall be free of charge for the recipient institution throughout the warranty period.
- The warranty period shall start from the date of acceptance by the end-user after testing and commissioning.
- Warranty covering all the delivered items including accessories and all the manufacturing defects and faults with only exception of misuse demonstrated by the Supplier.

Warranty shall cover all the services described in the following statements:

- Preventive maintenance and calibration on the equipment according to the manufacturers' recommendations. During preventive maintenance and calibration visits the supplier will shortly repeat and refresh the training for users and maintenance people.
- Corrective maintenance including all spare parts and labor and the consumables for testing.
- Guaranteed Uptime: Within the warranty period, the Supplier will guarantee at least 95% of Uptime (excluding interruptions due to maintenance or causes external to the system) for each equipment during a calendar year (that is, 347 days out of 365 days). The Supplier shall extend the total duration of the guarantee by a factor of 10 times the days that the equipment has been downtime above that five percent (5%) (18 days) per calendar year.
- The warranty will take place at the equipment location or at the official service facility of the supplier or manufacturer (whichever is faster for the repair of the equipment). Any cost of equipment transportation or technician travel expenses shall be at supplier's charge and included in the offered price.

- During the warranty period, if the equipment malfunctioning cannot be resolved remotely, an intervention on site will take place no longer than five (5) business days after the first communication about the issue. The Supplier shall extend the total of the guarantee in the same proportion for each additional day of delay.
- During the warranty period, should an equipment malfunctioning not be resolved within 30 calendar days a loan equipment shall be supplied to the Beneficiary meanwhile the malfunctioning is solved.
- After corrective and preventive maintenance visits, a report describing the technical procedures and results performed on the equipment shall be provided to the recipient institution.