

Section II: Schedule of Requirements

eSourcing reference: ITB/2024/53020

Section II.1: Summary of the required goods and services

Summary of the required goods and services is provided in the Annex 3 of the Draft Contract for Goods (see enclosed document "ITB-2024-53020_Section_IV_Draft_Contract_for_Goods").

Section II.2 Details of requirements that shall be assessed during the evaluation process:

Section II.2a - Manufacturer's Authorisation

To be eligible for the supply of goods, the bidder must be either the manufacturer of the offered goods or a sole representative of the manufacturer to UNOPS. Should offers for a particular make and model be received from more than one appointed representative, UNOPS reserves the right to select only one.

If the Bidder is not the manufacturer or producer of the Goods it offers to supply, s/he shall submit the Manufacturer's Authorization using the form included in Section III: Returnable Bidding Forms, Form E - Manufacturer's Authorisation Form - to demonstrate that it has been duly authorised by the manufacturer or producer of the Goods to submit a bid and supply the goods/products.

If the bidder is a manufacturer of one or more items, authorization(s) shall be required only for the balance of items from the respective manufacturers.

For Agents quoting in the name of a manufacturer of one or more lots(s): Proper authorization from the manufacturer for Bids from Agents plus legally enforceable authorization(s) for the balance of items from the respective manufacturers must be submitted.

Manufacturer's Authorisation shall be required only for the major equipment. Supply of non-critical parts, consumables, reagents, etc. shall not require manufacturer's authorisation.

Section II.2b - Manufacturer & Supplier Certification

For the purposes of this tender a supplier can either be a distributor (intermediary who does not manufacture but only provides the health product) or the manufacturer of a product.

Requirements for distributors: Distributors of medical devices and health products shall:

1. Have all the licences and authorizations required under national legislation of the country of operation issued by the national regulatory authority or other relevant entity; and
2. Have a Quality Management System (preferably compliant to ISO 9001 or other applicable quality management system requirements). Relevant certificates, licences, permits, authorisations or other documents, as may be applicable, attesting to existence of such QMS shall be provided as requested.

Requirements for Manufacturers: Manufacturers of In-vitro Diagnostic Devices (IVDs), Medical Devices (MDs) and other health products shall, subject to applicable regulations:

1. Have a duly authorised manufacturing licence, valid for all relevant manufacturing sites and activities performed, issued by the National Regulatory Authority of the country of manufacturing;
2. Have a valid and certified QMS, according to the following requirements:
 - a. latest versions in force ISO 13485 or any of the applicable ISO standards (ISO 9001), when the first is not applicable, or an equivalent QMS standard (equivalence defined below from b. to c.); and
 - b. latest version in force ISO 14001 for environmental management system or equivalent.
 - c. the QMS shall include the scope and the locations and facilities where the relevant activities are performed;
 - d. The QMS shall be issued by Conformity Assessment Bodies (CABs), Notified or Accredited bodies recognised by the Regulatory Authority of one of the founder / member countries of the Global Harmonization Task Force (GHTF) or the International Medical Device Regulators Forum (IMDRF) as a body continuing the GHTF's mission shall be recognised by such Authorities.

A valid copy of all the certificates shall be submitted.

Section II.2c - Product Certification

Compliance with internationally recognized standards of quality is expected for all the offered items. The Bid shall be accompanied with the Verified EU type Declaration of Conformity, issued by the manufacturer using the form included in Section III: Returnable Bidding Forms, Form J - Declaration of Conformity: - articulating the following:

- The name, serial number and model or type designation of the product;
- The name and address of the manufacturer (or the name and address of their authorised representative);
- The manufacturer's liability statement;
- If applicable, the details of the Notified Body that carried out the conformity assessment procedure;
- A list of the standards and regulations (Directives/Regulations) with which the product complies (e.g. ISO 14971, IEC 62366-1 or adequate);
- The date and place the statement was made;
- The full name, function and signature of the signatory.

The Manufacturer's Declaration of Conformity shall be accompanied by copies of the relevant certificates.