

Section II: Schedule of Requirements

eSourcing reference: ITB/2024/52887

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-2024-52887_Section_IV_Draft_Contract_for_Goods”).

Section II.2 Details of Service Requirements

The compliance to the requirements per item can be indicated by the supplier in the relevant Returnable Bid Schedule.

Section II.2a - Manufacturer's Authorisation

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 F - 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 item(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.

Authorisation must comply with the following:

- Offered on the letterhead of the manufacturer;
- Signed by an authorised representative of the manufacturer;
- Contact details of the manufacturer included;
- Clear authorisation from manufacturer to supplier for sales of designated item (brand + type), or sales of manufacturer's items in designated country confirming:
 - Manufacturer's full guarantee and warranty in accordance with Clause 5.5 of the General Conditions of Contract for the Provision of Goods and Services, with respect to the goods offered by the bidder;
 - Availability of spare parts, consumables, reagents etc and related service support in the Republic of Uzbekistan for the coming 5 years.

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 Medical Devices 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 and be Good

Manufacturing Practice (GMP) compliant according to the applicable regulatory framework and national regulations; and

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 standard (ISO 9001 etc.), when the first is not applicable, or an equivalent QMS standard (equivalence defined below from b. to c.); and
 - b. the QMS shall include the scope and the locations and facilities where the relevant activities are performed;
 - c. The QMS shall be issued by Conformity Assessment Bodies (CABs), Notified or Accredited bodies recognised by the Regulatory Authority of one of the Global Harmonization Task Force (GHTF) Founding Member countries (Australia, Canada, EU, Japan, US).
3. Have a valid and certified Environmental Management System, ISO 14001 or similar. Bidders shall submit copies of valid certificates for at least 1 manufacturer of the offered goods.

A valid copy of all the certificates shall be submitted.

Section II.2c - Product Certification and requirements

- Compliance with internationally recognized standards of quality is expected for all the offered items:
- Compliance and certification to Regulation (EU) 2017/745 (MDR) or Directive 93/42/EEC or FDA approval or EU Declaration of conformity with is required. Certificates must be issued in compliance with the regulatory frameworks of the founder countries of the Global Harmonization Task Force (GHTF).

Other product requirements:

- A technical file – which specifies its description, the justification for the instruments being Class I
- Product list with reference to technical descriptions
- Essential requirements checklist completed against 93/42/EEC
- Risk analysis that complies with 14971: 2007
- Copies of product labels that comply with BS EN 980

Section II.2d - Certificate of Registration/ Authorization/ Waiver for the import and use of MDs

Certificate of Registration/ Authorization/ Waiver for the import and use of the medical devices from the health regulatory authorities of the Republic of Uzbekistan (*State Center for expertise and standardisation of medicines, medical devices and medical equipment under the Ministry of Health of the Republic of Uzbekistan*) (hereinafter referred to as “Uzpharm Control”) and Sanitary & Epidemiological Welfare and Public Health Services of the Republic of Uzbekistan (hereinafter referred to as “SES”), must be obtained by the Supplier.

Information and links to the relevant sources and documents required for the registration of the medical devices are provided below:

- Website of the registering bodies: <https://www.uzpharm-control.uz/> and <https://www.sanepid.uz/>
- Decree of the Cabinet of Ministers of the Republic of Uzbekistan # 213 dd. 23/03/2018 “On approval of the regulation on the procedure for the state registration of medicines, medical products and medical equipment and the issuance of a registration certificate” (hereinafter referred to as “The Decree”) - <https://lex.uz/docs/3594815> with the following Annexes to the Decree:
 - Annex 1 - detailed description of registration process
 - Annex 2a - a template of Application Form
 - Annex 3a - list of the required documents
- State Register of Medical Products that have been already registered in the Republic of Uzbekistan - <https://www.uzpharm-control.uz/en/pages/state-register-of-medicines-and-medical-products>
- The decree of the President of the Republic of Uzbekistan #6221 d.d. 05 May 2021, Point #12 on the special process of registration of medical products certified by certain international organisations (see Appendix # 3 to the decree for the full list of organisations), according to which products with CE or FDA registration can be registered in Uzbekistan within 15 working days. <https://lex.uz/ru/docs/5411138#5419395>.
- Companies that provide services to suppliers for the registration of medicines and medical products in the Republic of Uzbekistan:

- <https://medexpert.group/>
- <https://www.pharmalex.uz/#services>
- <https://cratia.com/>
- <https://cerins.uz/ru/about>
- <https://medstandard.com.uz/services/>

Important note: The above information is obtained from open sources. UNOPS can neither recommend nor guarantee the quality of the services provided by any of these service providers.

Upon signature of contract with UNOPS for the supply of medical devices, the Contractor shall submit the application form(s) along with the required documents for registration to Uzpharm Control and SES and shall apply efforts to obtain the certificate(s) of registration or authorisation(s) or waiver(s) for the import and use of medical devices prior to goods' arrival to the country.

Section II.3: Delivery requirements

UNOPS Requirements	
Delivery time for the goods	Bidder shall make the goods available at FCA (Incoterms2020) point within 60 days after Contract signature and/or deliver them to DPU (Incoterms 2020) Tashkent, Uzbekistan within 90 days after Contract signature.
Delivery place and Incoterms rules	Bidder's quoted FCA point – FCA (Incoterms 2020) Tashkent, Uzbekistan – DPU (Incoterms2020)
Consignee details	Consignee details are provided in the Section IV: Draft Contract for Goods.
UNOPS Right to vary requirements	At the time the Contract is awarded, UNOPS reserves the right to vary the quantity of the goods and associated services specified above, provided this does not exceed +/- 20%, without any change in the unit prices or other terms and conditions of the RFQ.