

Section II: Schedule of Requirements

eSourcing reference: ITB/2024/54429

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

- 1.1. The list of the required goods includes 11 (eleven) lots, with quantities and specifications as referred to in Table 1 below. These items will have to be made available at the point of origin under FCA terms (Incoterms 2020) within **60 days** after the receipt of Order (signature of Contract) from UNOPS

Table 1

Lot #	Item Name	Q-ty
1	General Surgical Kit	22 Set
2	Gynaecological set	16 Set
3	Thoracic kit	1 Set
4	Plastic Kit	1 Set
5	Abdominal Set	1 Set
6	Urological set	1 Set
7	Head and Neck kit	1 Set
8	Orthopaedic set	1 Set
9	HPB Surgery Set	1 Set
10	Colorectal Kit	1 Set
11	Neurosurgery Kit	2 Set

- 1.2. If applicable, 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 Committee of the Republic of Uzbekistan (hereinafter referred to as "SES"), must be obtained by the Supplier.
- 1.3. Upon readiness of the goods at FCA point(s) of delivery, the Contractor shall then arrange transportation from FCA point(s) to DPU (Incoterms 2020) Tashkent, Uzbekistan. This transportation shall not take more than 30 days (90 days from Order receipt date).
- 1.4. Customs clearance of the shipments shall be the responsibility of the Consignee; however, the Contractor shall provide all the necessary documentation in a timely manner for facilitating the process. Contractor shall be held responsible for any financial loss resulting from failure to comply with

2. Details of Service Requirements

2.1. Warranty and After-sales Services

The Contractor shall submit a digital copy of the warranty certificate in the name of the Beneficiary before the item is shipped and the original together with the item, when shipped.

Warranty certificate shall clearly state equipment's serial number, warranty period and contact information of the local agent/representative of the Contractor. The warranty for all the equipment items shall remain valid for 24 months after the Goods have been fully installed and put into service, as certified by UNOPS.

The following conditions shall apply:

- The Contractor will ensure both remote (online) and on-site support, where necessary, for the maintenance of the supplied goods. This support shall be available during normal working hours of the hospital and shall be provided by the manufacturer or its authorised representative, as necessary.\

- Within the warranty period, the Contractor or its authorised service centre shall provide after sale service, including maintenance and/or replacement of defective parts/equipment, repair of equipment, labour for equipment repair and/or parts replacement in the equipment operation site not later than 5 (five) work-days from the date of receipt of phone call, written or E-mail notification from an authorised party. All maintenance shall be free of charge for the recipient institution throughout the warranty period.
- At least 95% uptime (full functioning) in a year, i.e. 347 days out of 365 days, will be guaranteed by the Contractor within the warranty period. In the event that the item supplied has been malfunctioning for more than five percent (5%) of one single year of the warranty period, i.e. more than 18 natural days in one single year, the Contractor shall extend the warranty period for a double (2x) duration of the equipment's downtime. Time required for customs clearance of a replacement part, if any, shall not be counted towards the downtime.

2.2. General Requirements

The following General Requirements are required to be adhered to:

Manual

The Contractor must provide a user manual with each item, in English and Russian Language. If not included in the user manual, the Contractor must provide a service manual with each item.

Transport and storage conditions

- Unless specifically indicated at the technical requirements of the item, the following conditions apply:
- Humidity ranges at least: 30% to 80%, continental.
- Temperature range at least: 15 – 25°C for equipment
- Indicate type of cargo - Normal Goods/Coldchain Goods/Danger goods.

Working conditions

Unless specifically indicated at the technical requirements of the item, the following working conditions apply (were applicable for the specific item):

- For single phase power requirement: 220V ± 10%, 50 Hz. Connector type F / Schuko (CEE 7/4).
- Humidity range at least: 30% to 80%, continental.
- Temperature range at least: 15 – 25°C.
- For equipment requiring water: Potable water pressure range acceptable at least between 1.2 - 1.8 bar.
- For IT equipment: ICT connector is RJ45, cable of minimum F/UTP 4x2xAWG24, CAT6A and providing 1 Gb/s minimum speed.
- Medical and lab equipment shall be resistant to cleaning and disinfection detergents, if the intended use requires cleaning and disinfection
- All mentioned equipment and software (if applicable) shall be supplied together with all drivers and connection cables foreseen by the design that is to enable its use as part of hardware complexes.

New products

- Contractor shall offer new, unused, most recent or current models and incorporate all recent improvements in design, software and materials unless explicitly agreed by UNOPS. Any outdated, obsolete, second hand or refurbished equipment will not be accepted.
- Contractor shall not offer equipment with recalls or safety alerts notified by international agencies such as the listed by the International Medical Device Regulators Forum (IMDRF)

Production date

- All medical and non-medical equipment items are to be new from the factory, produced in 2023 or 2022.
- All consumables, reagents, disposables, etc items delivered with the equipment items are to be delivered with a shelf-life and/ or expiration date of at least one year after delivery to UNOPS from Incoterm SPU, unless certain items can not have at least one year shelf-life, which shall be confirmed by the relevant product brochure or confirmation from the manufacturer.

2.3 All post-delivery services will be provided by the Contractor's local representatives, as follows:

- Full name: _____
- Address: _____
- Website address: _____
- E-mail: _____
- Contact person: _____
- Phone number: _____

3. Pre-shipment, packing, shipping and documentation requirements:

3.1. Schedule of supply activities:

Implementation Plan: Within 14 days after signature of Contract the Contractor shall submit a preliminary implementation plan (schedule) for all the activities. The plan shall be prepared in a table format. As a minimum, the schedule shall articulate the following on shipment-by-shipment basis:

- a) Item details (description, make and model, quantities, etc.)
- b) Production lead time in weeks or an exact date of goods' readiness at the manufacturing facility;
- c) Exact FCA (Incoterms 2020) point of delivery;
- d) Lead time for delivery to FCA;
- e) Expected weight/volume information with numbers and dimensions of packages/crates/cartons;
- f) Details of freight forwarder;
- g) Details of insurance and insurance provider;
- h) Mode of transport;
- i) Delivery route, transshipment points and border crossing points to DPU Tashkent, Uzbekistan;
- j) Expected delivery period and estimated delivery date from FCA point to DPU point;
- k) Delivery plan from Tashkent to the final destination;
- l) Plan of installation and training at the final destination;
- m) Details of any other important milestones and activities.

The Contractor shall be responsible for a weekly update of the implementation plan and shall keep UNOPS informed of any changes. Contractor shall be held responsible for any financial loss resulting from failure to comply with the timelines specified in the Contract.

3.2. Pre-shipment

- Good Manufacturing Practices (GMP) standards as set out by the WHO, where applicable, shall be adhered to, in all respects for manufacturing, packaging and labelling of products.
- The Contractor is required to provide, where applicable, UNOPS with the hazardous property sheet (MSDS or alike) and documents under which the quality assurance was processed in the Manufacturer's country, as shown in Operation and Service Manuals, within 2 weeks after award of contract.
- Photos of the cargo with packing labels shall be provided to UNOPS prior to handover to the freight forwarder.
- Invoices, packing lists, packing labels, BL/WB/AWB shall be submitted to UNOPS for approval before handover to the freight forwarder.

3.3. Packing and shipping instructions

Unless not applicable to the ordered products, the following packing and shipping instructions shall be followed:

- a) Ensure appropriate pilfer-proof export packing. All cases/crates must be wrapped inside with heavy-duty plastic-lined paper. Each case/crate/carton must be band strapped and able to withstand tough handling. Skids for truck handling are imperative if the gross weight is more than 30 kg.

- b) Consignment to be marked as per Consignee address shown in Clause 5.1.2 above. Additionally, each case/crate/carton must be marked with the final destination name provided in the Schedule of Requirements, attached hereto as Annex 3. Markings must be done with weatherproof material.
- c) Each case/crate/carton must carry a consecutive number, dimensions, volume and weight (i.e. Case No. X of Y cases, A x B x C cm, E m3, D kg). Markings must be done with weatherproof material.
- d) Partial shipment is allowed. Transshipment is allowed.
- e) Each case/crate/carton must carry outside a copy of the packing list describing the contents of the case/crate/carton. Outside case No. 1 a full set of invoices covering the actual delivery shall be attached. It is preferred that the accompanying papers be made out in English and/or Russian languages.
- f) Immediately upon shipment an e-mail must be sent to:
 - 1. United Nations Office for Project Services (UNOPS)
AUMCO Uzbekistan Office.
Address: 4A Afrosiyob Street, Tashkent, Uzbekistan
Email: yavdatv@unops.org
 - 2. Consignee: O'zbekiston Respublikasi Sog'liqni saqlash vazirligining "O'zbekiston Respublikasi onkologiya muassasalarini modernizatsiya qilish (II bosqich)" loyihasini amalga oshirish guruhi"
Davlat muassasasi (LAOG).
Address: 51, Parkent Street, Mirzo-Ulugbek District, Tashkent, Uzbekistan.
Phone: +998 (71) 268-25-39 (124)
Email: idb.uzb1021@gmail.com
Advising: Contract No., Project No., number of boxes/crates, total weight net/gross in kg, total cubic metres, ETD port of shipment, name of vessel, ETA to the final destination and including a copy of the invoice & shipping documents.
- g) All non-containerized goods must be shipped below deck, unless otherwise authorised by UNOPS.
- h) Bill of Lading shall be a Through Bill of Lading, when applicable, and always be marked "CLEAN ON BOARD" and "FREIGHT PREPAID". Bill of Lading must carry the following text under Shipper: "ON BEHALF OF UNOPS".
- i) For consumable items, the item must bear the Date of manufacture; and Expiry date.

3.4. Documents required

Two sets of shipping documents shall be issued and forwarded immediately upon shipment of goods, to the following addresses:

- **For custom clearance purposes only:** First set of shipping documents must be forwarded to:
United Nations Office for Project Services (UNOPS)
AUMCO Uzbekistan Office.
Address: 4A Afrosiyob Street, Tashkent, Uzbekistan
Email: yavdatv@unops.org
- a) (Through) Bill of Lading or Waybill in the name of Consignee - 1 original & 2 copies
- b) Shipping Invoice in the name of Consignee - 1 original & 2 certified copies
- c) Packing List - 2 copies
- d) Certificate of Origin - 1 original & 2 copies
- e) 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") for all the medical devices - 1 original & 2 copies
- f) Certificate of Compliance to Regulation (EU) 2017/745 (MDR) or Directive 93/42/EEC or FDA approval for all the medical devices - 2 certified copies.
- **For payment purposes only:** Second set of shipping documents must be sent to:
United Nations Office for Project Services (UNOPS)
AUMCO Uzbekistan Office
4A Afrosiyob Street, Tashkent, Uzbekistan
Phone: +998 71 205 1255

Email: yavdatv@unops.org

- a) (Through) Bill of Lading or Waybill in the name of Consignee - 1 certified copy
- b) Invoice in the name of UNOPS - 1 original & 2 certified copies
- c) Packing List - 2 copies
- d) Certificate of Origin - 1 copy
- e) 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") for all the medical devices - 1 copy
- f) Pre-loading inspection report - 1 original
- g) Signed Delivery Receipt(s) - 1 original

Important: Documents must arrive well in advance of goods. Contractor will be held responsible for any financial loss resulting from failure to comply with the above requirements. Payment will be effected within thirty (30) days of receipt of the above documents by this office.

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).

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 issued by NB 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 (coding, material No and material symbol, hardness and application according to EN ISO 7153:1-2016, DIN 10088-1/AISI F899 with coding tipisation of materials used)
- Essential requirements checklist completed against 93/42/EEC
- 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.