

## Section II: Schedule of Requirements (Rev1\_14June23)

eSourcing reference: RFQ/2023/45673

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

- The list of the required goods includes 13 (thirteen) items in total that are divided into 13 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	Specifications
1	Ultrasonic Surgical Dissector / Aspirator	1	See RFQ Section III - Returnable Bidding Forms - Form D - Technical Quotation Form, Lot 1
2	Ultrasonic Scalpel	2	See RFQ Section III - Returnable Bidding Forms - Form D - Technical Quotation Form, Lot 2
3	Set of instruments for ophthalmic surgery	1	See RFQ Section III - Returnable Bidding Forms - Form D - Technical Quotation Form, Lot 3
4	Surgical Binocular Loupe with light	5	See RFQ Section III - Returnable Bidding Forms - Form D - Technical Quotation Form, Lot 4
5	Set of equipment and instruments for laparoscopy	21	See RFQ Section III - Returnable Bidding Forms - Form D - Technical Quotation Form, Lot 5
6	RF ablation system	16	See RFQ Section III - Returnable Bidding Forms - Form D - Technical Quotation Form, Lot 6
7	Thermal Ablation system, Portable	72	See RFQ Section III - Returnable Bidding Forms - Form D - Technical Quotation Form, Lot 7
8	Multifunctional electro-surgery unit	5	See RFQ Section III - Returnable Bidding Forms - Form D - Technical Quotation Form, Lot 8
9	Surgical laser system for TUEB	1	See RFQ Section III - Returnable Bidding Forms - Form D - Technical Quotation Form, Lot 9
10	Power system for sternotomy	1	See RFQ Section III - Returnable Bidding Forms - Form D - Technical Quotation Form, Lot 10
11	Electro-surgery Unit	44	See RFQ Section III - Returnable Bidding Forms - Form D - Technical Quotation Form, Lot 11
12	Set of surgical Instruments	47	See RFQ Section III - Returnable Bidding Forms - Form D - Technical Quotation Form, Lot 12
13	Surgical Suction unit	44	See RFQ Section III - Returnable Bidding Forms - Form D - Technical Quotation Form, Lot 13

1

- Upon readiness of the goods at FCA point(s) of delivery, the supplier shall then arrange **transportation from FCA point(s) to DPU Tashkent, Uzbekistan**. This transportation shall not take more than **30 days (90 days from Order receipt date)**.
- 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 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>
- 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 successful supplier(s) 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 upon goods' arrival to the country.

4. Customs clearance of the shipments shall be the responsibility of the Consignee; however, the Supplier shall have to provide the necessary documentation in a timely manner for facilitating the process.
5. After clearance of the goods from Customs by the Consignee, the Supplier (or its nominated local agent, partner or subcontractor) shall be responsible for the associated **in-country logistics** ([i] transportation from customs depot to Supplier's warehouse including unloading; [ii] segregation of equipment by destination, [iii] loading, transportation and unloading to each destination hospital across Uzbekistan) including adherence to the cold-chain or temperature-control regime(s) required for the storage and transportation of the consumables, where necessary. Allocation of the equipment by final destinations (hospitals) is provided in Table 3 based on Codes of Hospitals noted in Table 2 below.

**Table 2 Code of Hospitals**

No	Description of health facility and its address	Code
1	Republican Specialized Scientific and Practical Medical Center of Oncology and Radiology (RSSPMCOR). Address: Shifokorlar Street, Almazar District, Tashkent city	D1
2	Syrdarya regional branch. Address: Gulistan city, Dustlik MFY, Khondamir street, 1	D2
3	Djizzakh regional branch. Address: Djizzakh region, Sharof Rashidov district, Samadova street, 6	D3
4	Kokand city regional branch. Address: Kokand city, Kukon Sadosi Ruznomasi street, 6	D4
5	Namangan regional branch. Address: Namangan city, Afrosiab street, 12	D5
6	Samarkand regional branch. Address: Samarkand city, Amir Shoh Murod street, 86	D6
7	Ferghana regional branch. Address: Fergana city, Gulistan street, 11	D7
8	Andijan regional branch. Address: Andijan city, Y. Atabekov street, 5	D8
9	Kashkadarya regional branch. Address: Karshi city, Chap sohil street, 28	D9
10	Navoi regional branch. Address: Navoi city, F. Mardonov street, 2	D10
11	Bukhara regional branch. Address: Bukhara city, Gijduvoni street, 71	D11
12	Surkhandarya regional branch. Address: Termez city, Ibn Sino street, 39	D12
13	Khorezm regional branch. Address: Urgench city, A. Bahodirhon street, 176	D13
14	Karakalpakstan regional branch. Address: Nukus city, Jumanazar street, 2	D14

**Table 3 Allocation by destinations**

Lot No	Lot Description	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	D11	D12	D13	D14	Total
1	Ultrasonic Surgical Dissector / Aspirator	1	-	-	-	-	-	-	-	-	-	-	-	-	-	1
2	Ultrasonic Scalpel	2	-	-	-	-	-	-	-	-	-	-	-	-	-	2

Lot №	Lot Description	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	D11	D12	D13	D14	Total
3	Set of instruments for ophthalmic surgery	1	-	-	-	-	-	-	-	-	-	-	-	-	-	1
4	Surgical Binocular Loupe with light	5	-	-	-	-	-	-	-	-	-	-	-	-	-	5
5	Set of equipment and instruments for laparoscopy	8	1	1	1	1	1	1	1	1	1	1	1	1	1	21
6	RF ablation system	3	1	1	1	1	1	1	1	1	1	1	1	1	1	16
7	Thermal Ablation system, Portable	11	5	5	1	5	5	5	5	5	5	5	5	5	5	72
8	Multifunctional electro-surgery unit	5	-	-	-	-	-	-	-	-	-	-	-	-	-	5
9	Surgical laser system for TUEB	1	-	-	-	-	-	-	-	-	-	-	-	-	-	1
10	Power system for sternotomy	1	-	-	-	-	-	-	-	-	-	-	-	-	-	1
11	Electro-surgery Unit	13	2	2	2	3	3	3	3	2	2	3	2	2	2	44
12	Set of surgical Instruments	16	2	2	2	3	3	3	3	2	2	3	2	2	2	47
13	Surgical Suction unit	13	2	2	2	3	3	3	3	2	2	3	2	2	2	44
	<b>Total:</b>	<b>80</b>	<b>13</b>	<b>13</b>	<b>9</b>	<b>16</b>	<b>16</b>	<b>16</b>	<b>16</b>	<b>13</b>	<b>13</b>	<b>16</b>	<b>13</b>	<b>13</b>	<b>13</b>	<b>260</b>

6. Once goods are delivered to final destinations, the Supplier shall then arrange for and carry out the **related services** (installation, assembly, calibration (where necessary), testing and commissioning and end-user training activities) in each hospital.
7. Whilst delivery from FCA point(s) to DPU Tashkent, Uzbekistan may be carried out in as many shipments as necessary, further deliveries from Tashkent to the final destinations (hospitals) shall be carried out in one shipment per destination or a group of destinations in order to reduce the disruption of the hospitals' operations. Similar to the foregoing, installation, assembly, calibration (where necessary) and end-user training activities in a given hospital shall be carried out in one go. These services, i.e. delivery of the goods from Tashkent to all the final destinations and performance of the related services at final destinations must be completed **within 60 days** after goods' arrival to Tashkent, Uzbekistan.
8. Storage in Tashkent, delivery to hospitals, storage at hospitals together with associated safety and security arrangements (including adherence to the cold-chain or temperature-control regime(s) required for the storage and transportation of the consumables, where necessary) for the goods until their handover to the authorities at each hospital shall remain the responsibility of the Supplier. The Supplier therefore should arrange for and maintain proper insurances for all the in-country storage and transportation activities.
9. In case the construction works at the hospital are not completed on time, UNOPS may request the Supplier to delay the shipment or the installation services and arrange for a temporary storage for the equipment either at origin or in Tashkent (or its vicinity). If UNOPS makes such a request, the Supplier shall be entitled to claim storage fees on "per CBM per day" basis.

## **Section II.2 Details of Service Requirements**

For the requirements indicated in Section II.1 this section provides the exact requirements to which the supplier must adhere. 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 standards (ISO 9001), 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 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.

**Manufacturer's commitment to sustainability:** It is preferred that at least half of the manufacturing facilities where the offered equipment are manufactured possess a valid ISO 14001 Environmental Management System (EMS) certificate. In the absence of ISO 14001, an EMS certificate issued by a competent national body can be considered.

**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:

- Compliance and certification to Regulation (EU) 2017/745 (MDR) or Directive 93/42/EEC or FDA approval is required. However, other certificates issued in compliance with the regulatory frameworks 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 are also acknowledged, if properly explained by the bidder (for all items offered/types of equipment).
- Specific Certification requirements are specified in the Technical Specifications of each particular item.

**A valid copy of the certificate(s) shall be submitted.**

**In addition to the product certificates, the awarded bidder shall be required to provide, where applicable, the hazardous property sheet (MSDS or alike) and documents under which the quality assurance is processed in the Manufacturer's country, as shown in Operation and Service Manuals of the offered equipment, within 2 weeks after contract signature.**

**Section II.2d - Assembly and Calibration**

- For Assembly and Calibration services, the bidder is required to provide the services adhering to the following requirements:
  - Work safely and manage all the installation works (including the use of heavy equipment, cranes, etc.) in line with UNOPS work safety rules provided in **Annex 1** of this Schedule.
  - Unpacking & clean-up, assembly (as applicable), calibration & testing (as applicable), commissioning (by a third party physicist), acceptance at each final destination place. Any consumables necessary for this procedure shall be included in the quote.
  - It shall be executed according to the applicable Republic of Uzbekistan's and international good practice rules..
  - Must be initiated within 7 calendar days after delivery of the equipment to each of the hospitals.
  - Must be carried out by a technician that is adequately qualified (FSE-Field Service Engineer certified by the Manufacturer). Installation by the Manufacturer shall be acceptable.

Post delivery services can be provided by the authorised national or regional Agent, which must be properly indicated in the applicable bid form as a subcontractor.

Post delivery services can be provided by the authorised national or regional Agent, which should be properly indicated in the applicable bid form as a partner (Returnable Form A) or subcontractor (Returnable Form C).

**Section II.2e - Online or On-Site Training Services**

Theoretical and practical training shall be provided in coordination with the relevant stakeholders no later than one (1) week after the goods are calibrated and ready to use. The training shall be provided either online or on-site as per the locations provided in Table 3 of Section II.1 where the venue of the training, minimum number of personnel to be trained, duration of each training, any other details shall be specified by the bidder.

- Two types of trainings are required:
  - User training on the items, so that users can understand and operate the device. This training shall be delivered to hospitals' specialists in Russian language for effective and problem-free use.
  - Service training on the equipment in Russian Language, so that end-users and/or technical personnel can understand how the device should be serviced, providing theoretical knowledge and practical skills necessary for the first level support as well as maintenance of the equipment including:
    - General safety instructions;
    - General instructions for the operation of the equipment;
    - Description of the basic principles of operation of the equipment, its design, installation and commissioning;
    - Knowledge of general and specific rules for preventive maintenance, replacement of spare parts, as well as troubleshooting/breakage.
- A proof of training (certificate) should be provided to the staff that is trained;



- Training services can be provided by the Manufacturer, the Supplier or its local Agent, which should be properly indicated in the applicable bid form as a subcontractor;
- The training shall be performed by qualified and authorised personnel;
- All training materials shall be provided in Russian. Translation of the documents into Russian shall be carried out in advance and shall be submitted to UNOPS for review at least 1 month prior to the start of the relevant training.

### **Section II.2f - Warranty and After-sales Services**

The bidder is required to have a local representative company in the country of destination (Uzbekistan). The name of the local partner or official representative responsible for providing the warranty services (if not performed by the manufacturer directly), contact person, address, telephone- and fax numbers, e-mail address must be mentioned in the bid.

The winning/most successful bidder shall be required to 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 bidder. 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 supplier 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 Supplier 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 Supplier 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 Supplier 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.

### **Section II.2g - General Requirements**

**The following General Requirements are required to be adhered to:**

#### **Manuals**

Bidders must provide a user manual with each item, in English and Russian languages. If not included in the user manual, Bidders must provide a service manual with each item. If documentation in Russian is not available at the time of bidding, bidders shall confirm in the relevant returnable bidding form that they shall provide the requested documentation in Russian together with the equipment.

#### **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/Cold chain Goods/Danger goods.

#### **Working conditions**

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

- For three phase power requirement: 380V ± 10%, 50 Hz.
- For single phase power requirement: 220V ± 10%, 50 Hz.
- Humidity range at least: 30% to 80%, continental.
- Temperature range at least: 15 – 25°C.

- 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 should be resistant to cleaning and disinfection detergents, if the intended use requires cleaning and disinfection
- All mentioned equipment and software (if applicable) should 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

- Bidders should 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.
- Bidders should not offer equipment with recalls or safety alerts notified by international agencies such as those 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 the last 24 months from tender closure date (April-2021 or later). Earlier production dates are NOT allowed.
- 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 the final destination, unless certain items cannot have at least one year shelf-life, which shall be confirmed by the relevant product brochure or confirmation from the manufacturer.

### Section II.3: Delivery requirements

UNOPS Requirements	
<b>Delivery time</b>	Bidder shall make the goods available at FCA (Incoterms2020) point within <b>60 days</b> after Contract signature and/or deliver them to Tashkent, Uzbekistan within <b>90 days</b> after Contract signature. Bidders shall perform the related services (installation, training, etc.) <b>within 60 days</b> after goods' arrival to Tashkent, Uzbekistan.
<b>Delivery place and Incoterms rules</b>	Bidder's quoted FCA point – FCA (Incoterms2020) Tashkent, Uzbekistan – DPU (Incoterms2020) Door-to-door from Tashkent to final destinations within Uzbekistan. Details of final destinations are provided in the Table 3 above.
<b>Consignee details</b>	Consignee details for the preparation of shipping documents shall be provided at the time of contract signature.
<b>UNOPS Right to vary requirements</b>	At the time the Contract is awarded, UNOPS reserves the right to vary the quantities of the equipment, components and consumables thereof, and associated services, provided this does not exceed +/- 20%, without any change in the unit prices or other terms and conditions of the RFQ.