

Section II: Schedule of Requirements- Lot 1

eSourcing reference: ITB/2023/49547

A. Summary of Requirements

Lot 1: Radio Protection Equipment

Radioprotection devices intended to be used in imaging services with intensive medical activities

B. Technical specifications for Goods and Comparative Data Table

Item No	Description	Quantity
1	Radioprotection set	3

General requirements for :

- Each device shall be CE marked,
- The manufacturer of **all** the equipment must be ISO 13485
- Conforms to the requirements as per MDR 745/2017 or MDD 93/42
- Copy of the above mentioned certifications shall be included in the offer.
- The supplier must provide Installation, User and technical manual in French preferably or English hard copy for the medical system during delivery on site.
- The supplier must provide with his/her offer the corresponding Price List of accessories, consumables and most significant spare parts for the items.
- **Associated services per site:**

C: DELIVERY AND INSTALLATION

The supplier is responsible and in charge of supplying and installing goods following the below listed minimal conditions:

- 1) DAP at the final user site for each equipment including unloading.
- 2) The bidder must request and include a **waiver of demurrage charges** at the port in Tunisia of at least 30 days.
- 3) The transportation must be done following the manufacturer guidelines (storage conditions , temperature, humidity, movementation requirements, battery management...) on how to handle the equipment, accessories, consumables and reagents when applicable:
- 4) Every single box delivered must be labeled as follow

3.a- Label on the boxes

The supplier has to ensure that the boxes are labelled as per requirements and with reference to the “principles of Labelling for Medical Devices and IVD Medical Devices”, IMDRF/GRRP WG/N52 FINAL:2019 <https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-190321-pl-md-ivd.pdf>

Region A Color code Region: A	Ministry of Health, TUNISIA UNOPS Office Xxxxxx , TUNIS, TUNISIA		
Beneficiary Hospital Data:	Tender: xxx	Lot xxx	Item xxx
Box	2	of	5
Box Weight kg	Length cm	Width	Height
xxx	xxx	xxx	xxx

3.b- Detailed Packing list of the box contents

The supplier has to ensure that the boxes are labelled as per requirements and with reference to the “principles of Labelling for Medical Devices and IVD Medical Devices”, IMDRF/GRRP WG/N52 FINAL:2019 <https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-190321-pl-md-ivd.pdf>

- 5) The boxes will be opened for contents check before starting the installation and a Report will be signed by the supplier and/or UNOPS:
- 6) All responsibility on the goods are transferred to the beneficiary Hospital once the installation, testing, training and commissioning is done and provisional acceptance documentation duly signed by Beneficiaries, UNOPS and Supplier representatives.
- 7) All the tools, instruments, products, solutions, simulators needed for the Transportation, Installation and testing as per manufacturer guidelines and country reglementation must be provided by the supplier during those activities.
- 8) Prior to shipment, the following documents should be sent to UNOPS:
 - · Bill of Lading
 - · Invoice
 - · Packing List

Once UNOPS confirms that the information is correct, then you may proceed with the shipment.

- 9) UNOPS reserves the right to perform Pre-Inspection (virtual or physic) checks before packaging of goods for delivery.
- 10) After the goods are shipped, the supplier must provide to UNOPS an updated delivery plan/schedule at least 2 weeks before DAP delivery on the final beneficiaries sites. UNOPS will facilitate the necessary authorizations and coordinate & confirm delivery dates with the beneficiary hospitals.
- 11) The supplier must be flexible enough to accommodate variations in the deliveries and installation schedule,

D: TESTING AND COMMISSIONING

The supplier is responsible and in charge of Testing the medical system or equipment following the below listed minimal conditions:

- 1) Testing of all the essential functions of the equipment or system complete of accessories with the appropriate tools, measurement equipment, simulators
- 2) Testing of all the technical data according to manufacturer testing guidelines.
- 3) Recording and archiving of all the testing data. The testing report and test results will be annexed to the provisional acceptance documentation.
- 4) Formal commissioning and provisional acceptance reports must be Co-signed by Supplier, UNOPS, MoH for each site with reference to all the medical equipment or system supplied. The general commissioning is done after the training except if the Hospital delays the training for more than 2 weeks.
- 5) The signed provisional acceptance document is the reference for the warranty period start date.
- 6) Waste management: The supplier is in charge of the safe removal and disposal of all the waste produced during his interventions.
- 7) All the tools, instruments, products, solutions, simulators needed for the installation testing as per manufacturer guidelines and country reglementation must be provided by the supplier during those activities.
- 8) The supplier must be flexible enough to accommodate perturbation or delays due to the medical activities in some sites during his intervention.

E: TRAINING REQUIREMENTS

For all the equipment and system provided, The supplier is responsible and in charge of providing appropriate training for users and biomedical technicians.

- Trainees: 8 users at each beneficiary site (surgeons and radiology nurse operators).
 - Training duration: minimum 1h (till mastering of the essential features and operations the medical system)
 - Training location: Beneficiary hospitals,
 - The Trainers must be a radioprotection product specialist
 - Credentials (certificates, cv,...) must be sent to UNOPS at least 7 days before the start of training.
- 1) Each trainee documentation in French, training accessories (pen, pencil, notepad) must be provided by the suppliers.
 - 2) All the video projectors, Parts, the tools, instruments, products, solutions, simulators, calibrators, internet needed for the training as per manufacturer guidelines and tender requirements must be provided by the supplier during those activities.
 - 3) A training report and attendance list must be produced to MoH & Unops
 - 4) Waste management: The supplier is in charge of the safe removal and disposal of all the waste produced during his interventions.
 - 5) The supplier must be flexible enough to accommodate perturbation or delays due to the medical activities in some sites during his intervention.

The training minimum objectives to achieve are:

a) Theoretical session

- Introduction to radioprotection
- Introduction to the equipment (general presentation, description)
- Presentation of the equipment parts and system components

- Risks or conditions leading to incorrect protection
- Common errors made by users during use of the equipment.
- How to set up the parameters How to configure the equipment or system
- How to interpret/understand messages/warnings
- Visual inspection, testing and cleaning

b) Demo - Hands On - Practical session

- Demonstration and hands-on use of all relevant safety devices (dosimeter functions, Lead apron...)

F: MAINTENANCE AND TECHNICAL SUPPORT REQUIREMENTS

For all the equipment and system provided, The supplier is responsible and in charge of

- Maintenance
- Technical support (remote/onsite) to the Hospital

These activities must be performed during the warranty year following the below listed minimal conditions:

- 1) All the Parts, the tools, instruments, products, solutions, simulators needed for the preventive maintenance, repairs as per manufacturer guidelines and country reglementation must be provided by the supplier during those activities.
- 2) After the Maintenances a general Testing of all the essential functions of the equipment or system complete with accessories with the appropriate tools, measurement equipment, simulators and Testing of all the technical and clinical data according to manufacturer testing guidelines must be performed.
- 3) An Intervention report must be produced to MoH & UNOPS after each intervention with indications of parts used code, tools, instruments, cost of the replacement parts or maintenance kits.
- 4) All the fees requested for providing the maintenance and technical support are supported by the supplier.
- 5) Waste management: The supplier is in charge of the safe removal and disposal of all the waste produced during his interventions.
- 6) The supplier must be flexible enough to accommodate perturbation or delays due to the medical activities in some sites during his intervention.
- 7) The provisional acceptance will be done after the full commissioning of the medical system and the final acceptance will be done with the beneficiary representative after the warranty year following the evaluation of the performance of the equipment and after sales services provided by the local or regional representative.

G: WASTE MANAGEMENT, HYGIENE, SECURITY AND SAFETY

The sites are functional hospitals with medical and logistical activities involving several categories of people, equipment and vulnerable infrastructures.

The supplier is responsible for the removal and safe disposal of all waste generated during its operations. Waste disposal must not be integrated into the beneficiary hospitals' waste processing chain.



- A preliminary waste management plan will be provided with the technical offer for evaluation. UNOPS reserves the right to request adjustments to the waste management plan in line with best practice in the country.
- A methodology or preliminary plan for the prevention of incidents and accidents involving materials, equipment and people during the supplier interventions (from delivery till commissioning) must be provided with the bid. UNOPS reserves the right to request adjustments to the plan in accordance with good safety and environmental management practices in force in the country.

The successful supplier will be required to take out an insurance policy covering accidents or incidents involving damage to persons or property in the beneficiary hospitals.

The supplier is responsible for the security of the materials, tools, equipment used to provide the requested services.

Item 1- Radioprotection set

Item No	UNOPS minimum technical requirements	Quantity
1	The Manufacturer of the proposed equipment are ISO 13485 certified	3
	Requirements: Electrical, Electromagnetic, Dimensions, documentation...	
	Provide a Regulatory approval and marketing authorization (FDA, CE); CE Certification as per MDR 745/2017 or MDD93/42	
	All system components must have FRENCH or ENGLISH as interface language	
	The medical system will be supplied with : User manual in French or English- electronic and hard copy as well as all user passwords	
	The medical system will be supplied with : Technical manual in French or English - electronic and hard copy as well as all technical / access passwords	
	Radiation Protection Items	
	Qty 2: Mobile shield The shield shall be mounted on 4 swivel wheels with brakes Unit provides full body shielding. Shield to be made of durable, easy-to-clean materials with liquid impermeable coating. The shield shall have an unbreakable, distortion-free and optically transparent top section made of leaded glass. The Leaded glass section have a height of at least 60 cm and 0.7 - 1.0 m width The Leaded glass section have an adjustable height indicatively From H 1.30 to H 2.00 m total height 2 mm lead thickness for bottom section and equivalent 2 mm lead thickness for leaded glass top section	
	Qty 2: Leaded glasses / goggles Protection of the central zones (front of the eyes) and lateral zones of the eyes. Lead equivalent: lenses 0.75 mm / lateral protections: 0.35 mm	

	<p>Qty 4: Direct-read programmable dosimeters for operators</p> <ul style="list-style-type: none"> - For regular monitoring of X-ray and γ-ray radiation levels. - Indicative dose range: 0.5 μSv - 9.99 Sv - Indicative dose rate range: 0.5 μSv/h - 3 Sv/h - Instantaneous digital display of cumulative dose and dose rate - Easily programmable by user: dose, dose rate, on / off, reset, alarm threshold setting - Adjustable dose and dose rate alarm thresholds - Power supply: batteries, over 50hrs autonomy - No calibration or maintenance required - 2-year warranty <p>Indicative measurements for lead aprons: Width : 60 cm, Length/height: 100 cm, washable.</p> <p>Qty. 4 : Large X-ray protective apron (Gown type), including shoulder cover with Velcro straps or solid clips. Lead equivalent of at least 0.5 mm Pb on front and at least 0.25 mm Pb on back at 100 kV.</p> <p>Qty 2 : Medium X-ray protective apron (Gown type), including shoulder cover with Velcro straps or solid clips. Lead equivalent of at least 0.5 mm Pb on front and at least 0.25 mm Pb on back at 100 kV.</p> <p>Qty 4 : Thyroid protection collars (2 medium; 2 large) Lead equivalent of 0.5 mm Pb at 100 kV.</p> <p>Qty 2 : Gonad belt (for patients) Lead equivalent of 0.5 mm Pb at 100 kV. Width ≥ 40 cm , length ≥ 40 cm.</p> <p>Qty 1: Mobile hanging cart for transporting aprons. At least 8 aprons holder positions</p> <p>Ancillary Services Included</p> <p>On-site delivery, installation , See Associated Services</p> <p>Testing & Commissioning, See Associated Services</p> <p>1 year warranty , technical assistance during the warranty year, See associated Services</p> <p>Training of medical staff, See Associated Services</p> <p>The images below are intended solely as a guiding support and should be considered as purely indicative and not restrictive of the expected item characteristics:</p> <div data-bbox="290 1476 670 1856" data-label="Image">  </div> <div data-bbox="764 1496 963 1852" data-label="Image">  </div>	
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H. Delivery requirements and Comparative Data Table

UNOPS Requirements	
Delivery time	Bidder shall deliver the goods 18 weeks after Contract signature.
Delivery place and Incoterms rules	Tunisia DPU (Consignee-wise quantity distribution list) UNOPS and/or the consignee will submit all tax exemption documentation to the selected supplier- The bidder must submit all shipment documents to UNOPS before departure of the shipment from the FCA point.
Consignee details	Ministry of Health in Tunisia
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 ITB.

Consignee-wise quantity distribution

Beneficiaries:

	Hospital	Ward Name:	Items	Quantity
BEN AROUS	CTGB	CHIRURGIE ORTHOPEDIQUE ET TRAUMATO	Radioprotection set	1
MANOUBA	Institut Mohamed Kassab d'Orthopédie	CHIRURGIE ORTHOPEDIQUE ET TRAUMATO	Radioprotection set	1
TUNIS	Hôpital des Enfants Bechir Hamza	CHIRURGIE ORTHOPEDIQUE ET TRAUMATO	Radioprotection set	1

Related services requirements

Service	UNOPS minimum requirements for services	Place where services will be performed	Final completion date(s) of services
1.	Delivery as per Distribution list	Tunisia (As per the distribution list)	Delivery should be made in fully as follows: - The Bidder shall deliver all the equipment no later than 18 weeks after contract signature.

2.	Installation		- The Bidder shall complete the installation for the units no later than 2 weeks after the delivery (20 weeks after the contract signature).
3.	Testing and Commissioning		Should be done at the end of the installation
4.	Preventive Maintenance, Corrective/Repair and technical assistance for users 1 year		Must be valid for 1 year (Warranty period)
5.	Training- Basic Start up training for end users		Should be done at the end of each installation (- Section E: TRAINING REQUIREMENTS)

I. Additional Inspections and tests

The following inspections and tests shall be performed:

The vendor must have the goods inspected in the manufacturer's works by a competent authority and submit a test certificate and also a guarantee/warranty certificate that the goods conform to written specifications.

UNOPS and/or its beneficiary representatives reserve the rights to conduct visits to the individual manufacturers' production premises to ensure and track the timely completion of their orders as per the defined quantities attributed to each scheduled deliveries. Those visits will be planned and coordinated with the manufacturers and constitute an important quality assurance step.

UNOPS or its representative reserve the rights to inspect and/or test any or all items of the goods to confirm their conformity to the contract, prior to dispatch from the manufacturer's premises. Such inspection and clearance will not prejudice the right of the consignee to inspect and test the goods on receipt at destination.

If the goods fail to meet the laid down specifications, the supplier shall take immediate steps to remedy the deficiency or replace the defective goods to the satisfaction of the purchaser.