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| <b>TERMS OF REFERENCE AND TECHNICAL SPECIFICATIONS</b> |
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**i. General information**

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|--------------------------------|-----------------------------------------------------------------------------------------------------------------------------|
| Assignment name                | <b>Supply, Delivery, Installation, Commissioning, Testing, Training, Warranty and Maintenance of a Thulium Laser System</b> |
| Beneficiary                    | <b>Medical Research and Care Center (MRCC), University of Mosul</b>                                                         |
| Country                        | <b>Mosul, Nineveh Governorate, Iraq</b>                                                                                     |
| Total estimated number of days | <b>90 calendar days</b>                                                                                                     |

The project "Support to Medical Care and Research Centre (MRCC)" of the University of Mosul aims to improve the health conditions of the population of Nineveh Governorate, by providing a range of health care and strengthening medical training with a view to national excellence. The main objective is to ensure the rehabilitation of the Centre's building and equipment so as to enable rapid start-up of diagnostic and external consultation activities in Mosul while guaranteeing international standards are followed.

The project focuses on the continuity of oncology healthcare services at MRCC by integrating rehabilitation activities and ensuring the on-time provision of essential medical equipment required for patient care and recovery.

The use of thulium fiber (TFL) lasers and pulsed-thulium YAG (p-Tm: YAG) lasers has represented a significant advance in endo-urological surgery over the past decade or so in endocorporeal laser lithotripsy (ELL). Clinical indications include urinary lithiasis and benign prostatic hyperplasia often as a first-line treatment. Other indications include tumors of the excretory urinary tract and tumors of the bladder, as well as certain stenosis.

They have replaced holmium YAG (Ho: YAG) lasers, with energy absorbed more selectively. Procedures can be performed percutaneously using a rigid endoscope or through natural orifices, with the advantage of no scarring and faster recovery.

There are therefore two types of thulium lasers: "fiber-coupled thulium" (TFL) and "pulsed thulium YAG" (p-Tm: YAG). Both can be proposed in this tender.

The endoscopic nature of their use necessitates strict sterilization protocols. Thulium lasers consist of a generator and optical fibers. These fibers are reusable provided they can be sterilized along with the associated endoscopes. They are also consumables that must be accounted for

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in the request for tender proposals. There are also single-use flexible optical fibers, which appear to be more expensive compared to those that can be sterilized.

### **ii.Context and justification of the need**

MRCC, a 150-bed research and therapeutic hospital located at the University of Mosul in Mosul-Ninawa Governorate, Iraq. MRCC is seeking a thulium laser device for completing its health basic offer to the population.

This endeavour aims to support and enhance the capacity of uro-cancer and uro-pathologies surgery and support services for different medical specialties in MRCC.

The targeted diseases are the following :

- Endoscopic resection of malignant bladder tumors
- Endoscopic resection of benign prostatic hyperplasia (BPH)
- Treatment of ureter and bladder stones using a semi-rigid endoscope
- Treatment of kidney stones using a flexible endoscope
- Endoscopic incision of urethral and ureteral strictures

### **iii.Objectives and desired results**

#### **1) General objective**

The expected objective of this device is to be used for approximately five (5) patients per week, totaling around two hundred (200) patients annually.

#### **2) Specific objectives**

In one full package of service to:

The objective is to procure a complete Thulium Laser System as a single package, including all required equipment, accessories, reusable laser fibers, consumables, installation, testing, commissioning, regulatory checks, warranty, software/firmware updates, maintenance, and training for end users and technical personnel.

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The proposal shall include the services below:

The services include:

- As mentioned above, the device is used in prostate surgery for removal of benign tumors, as well as removal of malignant bladder tumors. It is also used in endourological procedures for treating kidney, ureter, and bladder stones, in addition to incision of urethral and ureteral strictures.
- The required laser power is (60) watts for prostate surgery and kidney stone treatment.
- Laser fibers should be specific to the Thulium laser, preferably covering all sizes from small diameters (50–150 mm) for use with flexible endoscopes to larger sizes (550) for prostate treatment. The fibers should be reusable.
- The Thulium laser device must be compatible with the endoscopic equipment available in the operating room, including cystoscope, semi-rigid ureteroscope, flexible ureteroscope, nephroscope, resectoscope, morcellator, and video system.
- Essential safety accessories must be available, including protective goggles, laser warning signs, foot pedal, connectors, protective equipment, and quality control components.
- It is expected that approximately five (5) laser fibers for flexible and semi-rigid ureteroscopic and nephroscopic use will be consumed over 12 months, with a need for continuous maintenance.
- Availability of maintenance warranty from the manufacturer is required. A minimum two-year warranty covering labour, services and spare-parts replacement, including preventive and corrective maintenance, is required, An extension of the warranty may be proposed
- Completion of administrative procedures, on-site inspections, and necessary tests for regulatory compliance, commissioning, procedures with presets and calibrations. This includes the provision of consumables required for these tests.
- Clinical (MRCC medical and operational staff) and technical (MRCC technicians and engineering staff) training, including optimal use of software and patient throughput, security considerations, and technical first maintenance and quality control. The modalities must include any required travel and accommodation. Upon completion of the training, engineers and technicians shall be qualified to operate the equipment and perform the technical activities covered by the training within

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the limits of their authorization, within the limits specified by their authorization. They will also receive training materials.

- User and technical documentation (manuals, technical datasheets and relevant certificates) shall be provided in English. Arabic documentation shall also be provided where available.

### iv. Description of the assignment

#### 1) Planned activities.

The implementation of the thulium laser will be placed in the operating theater on the second floor of the building dedicated to kidney diseases, urological surgery, and kidney transplantation in the Research Hospital.

The operating room and designated unit are equipped with a power supply including UPS, laser safety requirements, smoke evacuation systems, and compatibility with endoscopic and anesthesia equipment. Laser safety procedures, access control, and personal protective equipment are also available. Additionally, facilities exist for cleaning, sterilization, and reprocessing of related instruments, as well as proper storage of fibers and consumables.

- These will **be completely covered by the successful bidder**. The latter carries out an installation study of its equipment in order to verify its compatibility with the premises and existing technical infrastructures. The successful bidder shall conduct a site assessment to verify the compatibility of the proposed equipment with the designated operating room and the existing technical infrastructure. Any installation-related MEP works and necessary architectural reinstatement/finishes required for the proper installation and operation of the Thulium Laser System shall be included in the bidder's scope, subject to prior approval by Expertise France/MRCC.

For all biomedical, infrastructure and MEP-related aspects, the Contractor shall cover:

- Site feasibility assessment;
- Supply, delivery and installation;
- Maintenance and warranty;
- All tests, inspections and approvals required by the competent local authorities for commissioning and final handover.

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### Assignment preparation

This contract is a public supply contract, aimed at the acquisition, delivery, installation (including necessary work), commissioning, warranty, maintenance, and training for thulium laser.

- Post-assignment follow-up: Follow up the implementation of the project according to the technical specifications

### 2) Anticipated deliverables

| Deliverables                                                                                                                                                           | End date                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| Technical documentation and plan for selecting the best equipment per site assessment.                                                                                 |                              |
| Methodology, layout, for new thulium laser device installation                                                                                                         |                              |
| Special technical details, layout and methodology for infra and MEP works of the specific room                                                                         |                              |
| Submit the delivery plan for the thulium laser system including the (Shipping, delivery to the site, installation, commissioning, warranty, maintenance and training). | mentioning the delivery date |
| Service job report                                                                                                                                                     |                              |
| Methodology for the taking-over of the equipment and the list of required tests to be done                                                                             |                              |
| Installation report                                                                                                                                                    |                              |
| Taking-over documents for all biomed, infra and MEP subjects                                                                                                           |                              |
| Maintenance plan                                                                                                                                                       |                              |
| Maintenance and warranty report at the end of the project                                                                                                              |                              |

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### **As part of the contract, each of the Bidders must:**

1. Define an activity schedule and the commissioning of the equipment proposed, with deadlines for delivery, installation and training.
2. Specify for each piece of equipment:
  - Environment conditions: evacuation, air-conditioning of the premises (temperature and hygrometry conditions, heat release of the equipment) and necessary extraction required per unit.
  - Necessary power supply.
  - Voltage (values, tolerance).
  - Frequency (values, tolerance).
  - Maximum power consumption.
  - The equipment suitable for working in the climate conditions of Iraq in terms of temperature & humidity.
  - Safety and fire equipment.

### **3) Coordination**

A technical kick-off meeting shall be held 15 days max after the contract is duly signed. Close collaboration must take place with personnel from assignment preparation right up to completion. Furthermore, regular exchanges must take place with contracting agency on assignment progress and any difficulties that may be encountered.

## **v. Duration and terms of performance**

1. **Implementation period:** Ninety (90) calendar days from the date of notification / commencement of the Contract.
2. **Estimated start date:** September 2026.
3. **Estimated completion date:** December 2026, subject to completion within the ninety (90) calendar-day implementation period.
4. **Schedule/program:** A detailed implementation schedule covering delivery, installation, testing, commissioning and training shall be submitted by the Contractor and approved by Expertise France.

## **vi. Required expertise and profile.**

### **A. General professional experience**

- The eligibility for participation in this tender is limited to companies that possess both the "Manufacturer's Authorization" and certification as an official distributor.

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- To be considered for this tender, companies must have technical teams capable of either traveling to or being based in Mosul. These teams will be responsible for the installation and training of medical staff in the MRCC.
- By submitting a proposal, the bidder agrees to fully and unconditionally accept the special and general conditions that govern this request for proposals and the proposed contract. The bidder acknowledges that these conditions, outlined in the contract, serve as the sole basis for this procurement process. Any other sales conditions are hereby waived by the bidder. Bidders are required to carefully review and adhere to all instructions, forms, contract provisions, and specifications provided in the tender dossier.
- It is strongly advised to thoroughly read and comprehend the tender rules document and its annexes. Failure to adhere to the procedures outlined therein may result in disqualification from the evaluation process

### **B. Technical quality (70%)**

#### **1. Company's capacity in Iraq (10 scores)**

- Iraq office = **2 scores**
- Staff number, composition and academic level qualification (at least 2 biomedical and 1 MEP engineers) = **2 scores**
- Surgical laser skills and experience of technicians and engineers = **2 scores**
- Similar Experience (Contracts) in supplying and installation of thulium laser equipment (5 years laser experience suggested) = **2 scores**
- Number and location of similar installed thulium laser systems in Iraq = **2 scores**

#### **2. Technical specifications of proposed devices (40 scores)**

- Thulium laser system type, power, specs = **30 scores**
- Ergonomics, size and footprint, quality of procedures with presets and calibrations, = **10 scores**

#### **3. Site preparation, installation, commissioning and warranty (10 scores)**

- Commissioning in real conditions of use and procedures with presets and calibrations. Including full documentation I certifications (English and Arabic) = **4 scores**

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- Training of clinical staff and surgical operating technicians and Local training of technicians and engineers of the hospital = **4 scores**
- Two years Warranty = **1 scores**

### 4. Medium- and long-term management of the thulium laser after-sales services (10 scores)

- Extension to three years maintenance conditions = **4 scores**
- Continuous education and development of skills for clinical and surgical staff (prescription and radiologist) and surgical laser operating technicians = **3 scores**
- Upgrade after 3 years (Hardware, Software and sequences) = **3 scores**

### C. Price (Financial Proposal): 30%

- Full and complete financial breakdown, total life cost including optic fibers, Commitment on the price of maintenance and on the price of spare parts for subsequent years = **30 scores**

## D. General articles and requirements

### ARTICLE 1: General requirements

- The bids must include all the equipment necessary for the correct operation of the device.
- All materials will be according to the international standards.
- The implementation will therefore be done at the optimum level to ensure the correct implementation of the installations, and the proper functioning from the start-up.

### ARTICLE 2: Authorization

The bidder must state whether it is a manufacturer, supplier, marketing company, or commercial agent in the authorization. If the company is a supplier, the following must be clarified:

- A. The names and specialties of the manufacturing companies must have authorizations certified by the manufacturing companies.
- B. If the marketing company is the supplier, a letter of authorization certified by the manufacturing companies is required.
- C. Manufacturers must state and classify the company's specialties (information specific to a specific system).
- D. A sole and exclusive representative to deal with for all its products must be stated. The company must also state the names of its factories and branches.
- E. The authorization letter must be certified.
- F. The authorization letter must be addressed to contracting agency.

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### ARTICLE 3: Manufacturer's Authorization Form

The authorization certificate must be attached to the Bidder's proposal includes the following format:

#### **MANUFACTURER S AUTHORIZATION FORM**

(to be submitted by authorized manufacturers/importers in a **letterhead**)

No. Dated:

To: Expertise France

MRCC / Medical equipment tender n°1 committee

Dear Sir / Madam,

Equipment/Item Name:

1. We ..... (Name of the OEM) are the original manufacturers of the above equipment having a registered office at ..... (Full address with telephone number/fax number & email ID and website), having factories at ..... and ....., do hereby authorize M/s. .... (Name and address of supplier) as submit bids, and subsequently negotiate, sign the contract and to supply, install & commission the above items with you against the above bid no.....

2. We also hereby undertake to provide full guarantee/warranty /CMC/AMC as agreed by the supplier in the event the Bidder is changed as the dealers, or the supplier fails to provide satisfactory after sales and service during such period of Comprehensive warranty/CMC/AMC and to supply all the spares/reagents / consumables for 5 years.

3. We also hereby declare that we have the capacity to manufacture and supply, install, and commission the quantity of the equipment s bided within the stipulated time.

(Name)

for and on behalf of M/s. ....

Date: (Name of manufacturers)

Place:

Seal

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### **ARTICLE 4: Training (Application and Service training):**

The offer must include full support: travel, accommodation, training costs, meals (lunch, accommodation) for the following personnel:

- End user (user training): The medical and paramedical team (day and night team).
- The Biomedical service (technical training): The biomedical engineer and/or the biomedical maintenance technicians (at least 3 persons)
- This will be sanctioned by a personal certificate, issued to each participant, stipulating that the level of skill required to ensure maintenance has been acquired by the technician.

During this training, all the necessary information must be provided:

- Complementary technical documentation.
- Set of computer access codes to the maintenance software, if applicable.
- List of the main spare parts to be kept in stock for MRCC
- The overall training offer must indicate the training schedule (periods, times) as well as the place and the planned training methods.

The Bidder also undertakes to train again, at his own expense, the user, medical and biomedical teams, in the event of changes to the devices supplied (hardware or software changes). The training may be postponed of several months after the installation and commissioning phases, if the biomedical and technical teams of the MRCC are not designated yet.

### **ARTICLE 5: Organization of delivery, installation, and commissioning reception**

The delivery of equipment to the service premises, assembly, installation and commissioning are the responsibility of the Bidders, they must explicitly show the conditions of ground load, electrical power supply, average power, peak power absorbed, the tolerable temperature in each room (in particular the maximum tolerable variation gradient).

The mandatory tests and inspections for the commissioning of the equipment and the verification of their performance will be carried out before receipt according to the manufacturer's recommendations and the regulations in force. The cost of these operations is the responsibility of the Bidder.

CONTRACTING AGENCY shall bear no responsibility over losses or damages of the procured products incurred during the performance period and before acceptance of said products. The bidder bears the responsibility to verify and certify that the goods they supply are in keeping with the conditions applicable to them.

Before each delivery, the bidder must submit a copy of the delivery note and all the shipping documents detailed, at least 15 days prior the arrival of the device to the site in order to get the

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formal agreement from end user to deliver the goods. For every consignment, the bidder shall always send a delivery note. Delivery slips shall necessarily bear the Contract Reference, batch numbers, serial numbers if any, the full designation and quantities of the delivery.

Added to the delivery note, the selected bidder will also have to provide with:

- a delivery notes and / or Packing List
- a commercial invoice
- a Certificate of Origin from the manufacturer.
- a Certificate of Conformity or Certificates of Analysis (if applicable)
- other documents.

The Bidder commits to inform Contracting agency any constraint or specific regulation linked to the goods or service supply or to the country of importation.

The Bidder will inform Contracting agency CONTRACTING AGENCY about all quality certifications, labels (NF, ISO, CE...) and internal quality process that may apply to its goods or services and will supply all official documents upon Contracting agency request.

### *Non-conformity of delivery*

Should the quality or the condition of the products not satisfy CONTRACTING AGENCY requirements at the moment of the preliminary inspection or delivery inspection, CONTRACTING AGENCY reserves the right to demand:

- The delivery of products which conforms to the order. They will need to be replaced by the Bidder at his/her own expenses. The replacement will be executed as soon as possible, at latest within fifteen (15) calendar days from the discovery of the non-compliance (from the issuing of a certificate of non-conformity). The replaced products will again be subject to the rules laid down in this contract, including the twelve (24) month guarantee (IF APPLICABLE)
- Or the immediate reimbursement of the payment
- Or the cancellation of the order and of the corresponding price.

## ARTICLE 6: Upgrade

The homogeneous evolution of all the equipment is planned with this contract. This evolution concerns both the hardware part, software and accessories.

For each of the products and software offered, the Bidder will list the major hardware and/or software developments already implemented since the date of first commissioning. It will imperatively be indicated the version of the software provided. The Bidder will specify which hardware and/or software developments are planned, detailing:

- the nature of the expected change,
- the methods of implementation,
- the planned publication date or the planned periodicity,
- the approximate additional implementation cost.

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The Bidder will also indicate which characteristics (technology, architecture, etc.) facilitate the subsequent development of the products offered. The Bidder will specify the terms of support for upgrades, hardware and software developments and undertake to do so contractually.

The Bidder will commit in particular to the tariffs and/or the minimum discount rates which will be practiced during the operation of the equipment. In the event of technological development of its products, during the period of execution of the contract, the selected bidder may propose to substitute a new product for the old one. This substitution can only be effective after written acceptance by the manager of the establishment and without change in the unit price.

### ARTICLE 7: Medical equipment fitting and Room layouts (loaded drawings)

The Bidder must provide the medical equipment that will be fitted according to room layout. In this tender, the specific room details will be provided later to recognize the equipment locations.

#### vii. Assignment reports

A report following the model provided must be forwarded by e-mail on conclusion of the assignment: it must correspond with the deliverable summary analytical report.

#### viii. Monitoring-evaluation

##### Performance indicators

| Deliverables | Immediate effects | Intermediate effects | Verification sources |
|--------------|-------------------|----------------------|----------------------|
|              |                   | X                    |                      |

#### ix. Personal Protective Equipment (PPE) for Construction

Required personnel protection equipment (PPE) must be always worn when on construction or renovation sites at Mosul University. At a minimum, each employee is required to wear a hard hat and safety glasses. High visibility safety vests with reflective striping are required when employees are exposed to vehicular traffic. In the absences of vehicular traffic, high visibility shirts should be always worn. All workers must wear shirts with sleeves, long work pants, and sturdy work shoes or boots when working on a construction or renovation site. Sleeveless or tank top shirts, short pants, sweatpants, sneakers, sandals, and high-heeled or open-toed shoes are

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not permitted. Depending on the circumstances and potential hazards present, additional PPE may be required:

Specific protective clothing such as welding leathers when welding or FR clothing when working with live electric.

### x. Technical Data Instructions

For the submission of bids, each candidate will propose a plan layout of the proposed equipment. The layout will make it possible to check the ergonomics of the rooms by showing the effects of handling of the thulium laser installation requirements. **The implantation and installation layout will be required.**

#### I

#### I.1.2 General technical description

##### Objective Standards and Regulations

##### Standards and regulations

Medical devices, their components, and the services provided must comply with all applicable standards and regulations mentioned in this section on the date of contract signature, as well as those applicable at the time of final acceptance of equipment and services:

- ISO 13485:2003 Medical devices -- Quality management systems -- Requirements for regulatory purposes (Australia, Canada and EU)
- ISO/TS 10974
- IEC 60601-2-33

##### **CE marking**

All equipment, peripherals, accessories and consumables will comply with the regulations relating to Directive 93/42/EEC.

The installation must be in accordance with standards and all the regulations in force (hygiene, machine safety, electrical safety, etc.).

Each medical device and pressure device will be accompanied by CE declarations and CE type-examination certificates with the limit of validity and recurrence of controls.

##### **FDA clearance (Preferred) and ISO certificates**

The required certificates are to be provided.

##### **Out-of-warranty maintenance:**

The Bidder will specify in his offer the elements relating to the support of out-of-warranty maintenance with an offer including:

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- Training of the technical team in curative and preventive maintenance of equipment.  
The equipment and conditions of realization necessary for a support by the maintenance service of MRCC.
- labor, parts (excluding consumables) for support by the bidder's after-sales service, for maintenance from level 2.

The services are carried out in partnership with the technical staff of the Biomedical department of the **MRCC medical centers** according to their availability. However, MRCC reserves the right to involve the contracting party if necessary. **The Bidders will indicate in his offer the amounts relating to this type of intervention.**

### **Annexes:**

1. **Annex Thulium Laser scoring.**



- 2.