**Annex 1**

**Technical Specifications**

**Lot 1:**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Ultrasound Apparatus (General)** | | | | | | **Q-ty: 1** | | |
| Purpose : Ultrasonography for an adult patient. | | | | | | | | |
| **1. COMPOSITION** | | | | | | | | |
| 1-1Composition | | | | | | | | |
|  | (1) | Main unit with system control software | | : | 1 unit | | | |
|  | (2) | Probe A | | : | 1 unit | | | |
|  | (3) | Probe B | | : | 1 unit | | | |
|  | (4) | Probe C | | : | 1 unit | | | |
|  | (5) | B/W Printer | | : | 1 unit | | | |
| 1-2 Accessories | | | | | | | | |
|  | (1) | Probe hanger and loader. | | | | | | |
|  | (2) | Software for measurement is included in the system. | | | | | | |
|  | (3) | Software for DICOM (storage and transfer) is included in the system. | | | | | | |
| **2. SPECIFICATIONS** | | | | | | | | |
| 2-1 Main unit | | | | | | | | |
|  | (1) | Scan mode | : Linear, Convex, Phased (Sector) | | | | | |
|  | (2) | Monitor | : LCD color ≤21 inch | | | | | |
|  | (3) | Frequency range accepted by the system | : ≥1-18 Mhz | | | | | |
|  | (4) | Dynamic range | :180 dB | | | | | |
|  | (5) | Gray scale resolution | : ≥256 | | | | | |
|  | (7) | Number of active probe connector | : ≥3 | | | | | |
|  | (8) | System recognized probes | : Linear array, convex array, TEE, intraoperative, sector array, volumetric, 4D array, pencil. | | | | | |
|  | (9) | Power supply | : AC 220V ±10%, single phase, 50 Hz | | | | | |
| 2-2 Probe A | | | | | | | | |
|  | (1) | Type | : Convex | | | | | |
|  | (2) | Frequency range | : 1-5 MHz or larger | | | | | |
|  | (3) | Biopsy adapter | : equipped | | | | | |
|  | (4) | Max. scanning depth | : ≥30 cm | | | | | |
| 2-3 Probe B | | | | | | | | |
|  | (1) | Type | : Endocavitary | | | | | |
|  | (2) | Frequency range | : 4-8 MHz or wider | | | | | |
|  | (3) | Biopsy adapter | : equipped | | | | | |
| 2-4 Probe C | | | | | | | | |
|  | (1) | Type | : Linear | | | | | |
|  | (2) | Frequency range | : 5-14 MHz or wider | | | | | |
|  | (3) | Biopsy adapter | : equipped | | | | | |
|  | (4) | Scanning width | : 35 mm or more | | | | | |
| 2-5 Scanning Modes | | | | | | | | |
|  | (1) | 2D mode | : equipped | | | | | |
|  | (2) | 2D real-time Doppler echocardiography | : equipped | | | | | |
|  | (3) | B-flow | : equipped | | | | | |
|  | (4) | M-mode | : equipped | | | | | |
|  | (5) | Spatial Compound Imaging | : equipped | | | | | |
|  | (6) | Differential Tissue Harmonic Imaging (DTHI) | : equipped | | | | | |
|  | (7) | Tissue Harmonic Imaging (THI) | : equipped | | | | | |
|  | (8) | Pulse wave Doppler | : equipped | | | | | |
|  | (9) | Color doppler mode | : equipped | | | | | |
|  | (10) | Superb micro-vascular imaging | : equipped | | | | | |
|  | (11) | Advanced dynamic flow | : equipped | | | | | |
|  | (12) | Power Doppler | : equipped | | | | | |
|  | (13) | Duplex | : equipped | | | | | |
|  | (14) | Triplex | : equipped | | | | | |
|  | (15) | Shear wave elastrography | : equipped | | | | | |
| 2-6 Functionalities | | | | | | | | |
|  | (1) | Adjustable transmit focus | : equipped | | | | | |
|  | (2) | Dynamic receive focusing | : equipped | | | | | |
|  | (3) | Microcalcification visualization | : equipped | | | | | |
|  | (4) | Reduced micro-vascular flow imaging | : equipped | | | | | |
|  | (5) | Panoramic regime | : equipped | | | | | |
|  | (6) | Possibility of performing measurements in a recorded video | : equipped | | | | | |
| 2-7 PAN/ZOOM | | | | | | | | |
|  | (1) | Real time zoom | : equipped | | | | | |
|  | (2) | Magnification of a frozen ultrasound image | : equipped | | | | | |
| 2-8 Storage | | | | | | | | |
|  | (1) | Internal capacity | : ≥500 GB | | | | | |
|  | (2) | Storage of images and videos directly on a USB memory stick | : equipped | | | | | |
| 2-9 Exam Presets | | | | | | | | |
|  | (1) | Abdominal | : equipped | | | | | |
|  | (2) | Urologic | : equipped | | | | | |
|  | (3) | Shear wave elastography | : equipped | | | | | |
|  | (4) | Musculoskeletal | : equipped | | | | | |
|  | (5) | Vascular | : equipped | | | | | |
|  | (6) | Visualization of small objects | : equipped | | | | | |
|  | (7) | Visualizations of microcalcifications | : equipped | | | | | |
|  | (8) | Fetal/Obstetric | : equipped | | | | | |
|  | (9) | Gynecological | : equipped | | | | | |
|  | (10) | Cardiac | : equipped | | | | | |
|  | (11) | Renal | : equipped | | | | | |
|  | (12) | Pediatric | : equipped | | | | | |
| **3. QUALITY ASSURANCE REQUIREMENTS** | | | | | | | | |
|  | (1) | EC Certification | | | | | | |
|  | (2) | Compliant to IEC 60601-1, 60601-2 and other applicable EU standards | | | | | | |
|  | (3) | Manufacturer ISO 13485 | | | | | | |
|  | (4) | Declaration of conformity with guideline 93/42/EEC | | | | | | |
| **4. SPARE PARTS** | | | | | | | | |
| No | | | | | | | | |
| **5. CONSUMABLES** | | | | | | | | |
|  | (1) | Echo gel | | | | | : | 5 L |
|  | (2) | Printer paper | | | | | : | 12 rolls |
| **6. NOTES** | | | | | | | | |
| Warranty at least 12 months for the equipment and probes. | | | | | | | | |
| Equipment assembly, installation and commissioning on site at beneficiary location | | | | | | | | |
| User’s manuals, preferable in Romanian or Russian language (optional English) | | | | | | | | |
| Maintenance manual, preferable in Romanian or Russian language (optional English) | | | | | | | | |
| Any additional component or accessory which is required for adequate installation and operation should be included and described on your offered specification | | | | | | | | |

**Lot 2**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Arhroscope** | | | | | **Quantity: 1** |
| Purpose : | | Equipment for minimally invasive for joints surgeries. | | | |
| **1. COMPOSITION** | | | | | |
| 1-1 Composition | | | | | |
|  | (1) | Telescope | : | 1 unit | |
|  | (2) | Trocar with sheath | : | 1 pc | |
|  | (3) | Light source | : | 1 units | |
|  | (4) | Fiber optic light cable | : | 2 unit | |
|  | (5) | Video camera head | : | 2 units | |
|  | (6) | Video camera control unit | : | 1 unit | |
|  | (7) | HD Monitor | : | 1 unit | |
|  | (8) | Trolley | : | 1 unit | |
| 1-2 Accessories | | | | | |
| Any additional component or accessory which is required for adequate installation and operation should be included and described on your offered specification | | | | | |
| **2. SPECIFICATIONS** | | | | | |
| 2-1 Telescope | | | | | |
|  | (1) | Type | : | Autoclavable | |
|  | (2) | View direction | : | 30̊ | |
|  | (3) | Diameter | : | 4 mm | |
|  | (4) | Working length | : | 140-180 mm | |
|  | (5) | Lighting | : | Fiber optic transmission units | |
| 2-3 Trocar with sheath | | | | | |
|  | (1) | Trocar | : | applicable for 2-1 | |
|  | (2) | Diameter | : | 6.0 mm | |
|  | (3) | Working length | : | 130 mm | |
| 2-4 Light source | | | | | |
|  | (1) | Type of light source | : | LED | |
|  | (2) | Light transmission method | : | Fiber optic cable | |
| 2-5 Fiber optic light cable | | | | | |
|  | (1) | Diameter | : | 3.5 mm or more | |
|  | (2) | Length | : | 200 cm or more | |
| 2-6 Video camera head | | | | | |
|  | (1) | Resolution | : | 1080p or higher | |
|  | (2) | Type | : | Autoclavable | |
|  | (3) | Controls | : | 2 programable control buttons | |
| 2-7 Video camera control unit | | | | | |
|  | (1) | Resolution | : | 1080p or higher | |
|  | (2) | Light source | : | LED | |
|  | (3) | Adapters | : | For 4 different types of lighting cables | |
|  | (4) | USB | : | Equipped | |
|  | (5) | Fiber optic light transmission | : | Equipped | |
| 2-8 HD Monitor | | | | | |
|  | (1) | Size | : | 26" or more | |
|  | (2) | Resolution | : | 1080p or more | |
| 2-9 Trolley on castors | | | | | |
|  | (1) | Application | : | For installation of light source, video camera control unit, image management unit, LCD monitor, electrosurgical generator and irrigation pump or more | |
|  | (2) | Integrated electrical sockets | : | Equipped | |
|  | (3) | Mobile support for the power suction | : | Equipped | |
|  | (4) | Earth leakage monitor or similar current protection tool | : | Equipped | |
|  | (5) | Antistatic castors with brakes | : | Equipped | |
| **3. QUALITY ASSURANCE REQUIREMENTS** | | | | | |
|  | (1) | EC Certification |  |  | |
|  | (2) | Manufacturer ISO 13485 |  |  | |
|  | (3) | Declaration of conformity with guideline 93/42/EEC | | | |
|  | (4) | Warranty at least 12 months |  |  | |
| **4. SPARE PARTS** | | | | | |
| 4-1 Not required | | | | | |
| **5. CONSUMABLES** | | | | | |
| 5-1 Not required | | | | | |
| **6. NOTE** | | | | | |
| Equipment assembly, installation and commissioning on site at beneficiary location | | | | | |
| User’s manuals, preferable in Romanian or Russian language (optional English) | | | | | |
| Maintenance manual, preferable in Romanian or Russian language (optional English) | | | | | |
| Compatible with arthroscopy set | | | | | |

**Lot 3**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Arthopaedic bone drill** | | | **Quantity: 1** | | |
| Purpose: Battery operated drill machine intended for orthopaedic and trauma applications. | | | | | |
| **1. COMPOSITION** | | | | | |
| 1-1 Composition | | | | | |
|  | (1) | Rotary handpiece | | : | 1 unit |
|  | (2) | Drilling attachments | | : | 1 unit |
|  | (3) | Reaming attachements | | : | 1 unit |
| 1-2 Accessories | | | | | |
|  | (1) | Battery | | : | 1 unit |
|  | (2) | Sterile battery kit | | : | 2 units |
|  | (3) | Battery charger or charging station | | : | 1 unit |
|  | (4) | Sterilization case | | : | 1 unit |
| Any additional component or accessory which is required for adequate installation and operation should be included and described on your offered specification. | | | | | |
| **2. SPECIFICATIONS** | | | | | |
| 2-1 Drill | | | | | |
|  | (1) | Power output | | : | ≥ 90W |
|  | (2) | Drill speed | | : | ≥ 1000 RPM |
|  | (3) | Torque | | : | ≥ 2.9 Nm |
|  | (4) | Battery | | : | equipped |
| **3. QUALITY ASSURANCE REQUIREMENTS** | | | | | |
|  | (1) | Protection class | | : | EN/IEC 60601 |
|  | (2) | Protection class by casing | | : | IPX7 or better |
|  | (3) | EC Certification | |  |  |
|  | (4) | Manufacturer ISO 13485 | |  |  |
|  | (5) | ISO 9714 | |  |  |
|  | (6) | Warranty at least 12 months | |  |  |
| **4. SPARE PARTS** | | | | | |
|  | (1) | Autoclavable oscillating engine | | : | 1 unit |
|  | (2) | Autoclavable rotary, 2-way, cannulated rotation motor | | : | 1 unit |
|  | (3) | Rechargeable batteries | | : | 1 unit |
|  | (4) | Chargers | | : | 1 unit |
| **5. CONSUMABLES** | | | | | |
| Not required | | | | | |
| **6. NOTE** | | | | | |
| Can be autoclaved up to 135 degrees Celsius. | | | | | |

**Lot 4**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Shaver system for orthopaedics** | | | | | **Quanity: 1** | | |
| Purpose : Universal device console for connecting power-assisted shaver, drill and saw tools. | | | | | | | |
| **1. COMPOSITION** | | | | | | | |
| 1-1 Composition | | | | | | | |
|  | (1) | Shaver console | | : | | | 1 unit |
|  | (2) | Handpiece | | : | | | 1 unit |
|  | (3) | Foot switch | | : | | | 1 unit |
| 1-2 Accessories | | | | | | | |
| Any additional component or accessory which is required for adequate installation and operation should be included and described on your offered specification. | | | | | | | |
| **2. SPECIFICATIONS** | | | | | | | |
| 2-1 Motor system for orthopaedics | | | | | | | |
|  | (1) | Shaver console | | : | | | \*Equipped |
|  | (2) | Shaver allows clock and counterclockwise rotations | | : | | | Equipped |
|  | (3) | Shaver clockwise rotation | | : | | | min 8000 rpm |
|  | (4) | Shaver counterclockwise rotation | | : | | | min 8000 rpm |
|  | (5) | Shaver' modes of oscillations | | : | | | 7 or more |
|  | (6) | Shaver blade diameter | | : | | | \*\*from 2 to 8 mm at least 5 different sizes |
|  | (7) | Clockwise, counterclockwise and oscillation handpiece rotation modes | | : | | | Equipped |
|  | (8) | Ergonomic and autoclavable handpiece | | : | | | Equipped |
|  | (9) | Automatic detection of a connected handpiece | | : | | | Equipped |
|  | (10) | Handpiece connection to control unit | | : | | | wired or wireless |
|  | (11) | The shaver system can be controlled by a footswitch | | : | | | Equipped |
|  | (12) | Memory storage | | : | | | Equipped |
|  | (13) | Handpiece equipped with 2 buttons, each having double functionality | | : | | | Equipped |
|  | (14) | Power requirements | | : | | | AC 220V±10%, single phase, 50Hz |
| **3. QUALITY ASSURANCE REQUIREMENTS** | | | | | | | |
|  | (1) | EC Certification | |  | | |  |
|  | (2) | Compliant to EN 60601-1, 60601-2 and other applicable EU standards | | | | | |
|  | (3) | Manufacturer ISO 13485 | |  | | |  |
|  | (4) | Declaration of conformity with guideline 93/42/EEC | |  | | |  |
|  | (5) | EN 60529, IPX (7,8) testing | |  | | |  |
|  | (6) | Warranty at least 12 months | |  | | |  |
| **4.SPARE PARTS** | | | | | | | |
|  | Not required | |  | | |  | |
| **5. CONSUMABLES** | | | | | | | |
|  | (1) | Reusable shaver blades | | : | | | ≥ 5 |
| **6. NOTE** | | | | | | | |
| \*Console compatible with the handpiece and foot switch. | | | | | | | |
| \*\*Selection of the blades and endings (resectors, burrs or cutters) will be made by the beneficiary after awarding the bidder | | | | | | | |
| Equipment assembly, installation and commissioning on site at beneficiary location | | | | | | | |
| User’s manuals, preferable in Romanian or Russian language (optional English) | | | | | | | |
| Maintenance manual, preferable in Romanian or Russian language (optional English) | | | | | | | |

**Lot 5**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Suction-irrigation unit** | | | **Quantity: 1** | | |
| Purpose :Ensures fluid management control during arthroscopic procedures. | | | | | |
| **1. COMPOSITION** | | | | | |
| 1-1Composition | | | | | |
|  | (1) | Suction-irrigation unit | | : | 1 unit |
|  | (2) | Suction bottles | | : | 2 pcs |
|  | (3) | Tubing for the irrigation channel | | : | 5 sets |
|  | (4) | Remote control | | : | 1 unit |
|  | (5) | Dual pedal foot switch for irrigation unit or similar | | : | 1 unit |
| 1-2 Accessories | | | | | |
|  | (1) | Tube kit for suction | | : | 1 set |
|  | (2) | Tube kit for irrigation | | : | 1 set |
|  |  | Any additional component or accessory which is required for adequate installation and operation should be included and described on your offered specification. | | | |
| **2.SPECIFICATIONS** | | | | | |
| 2-1 Suction-irrigation unit | | | | | |
|  | (1) | Ergonomic and autoclavable handpiece with suction knob | | : | Equipped |
|  | (2) | Touch screen control display | | : | Equipped |
|  | (3) | Suction-irrigation handpiece allows 3 modes of work: standard, efficient and aggressive | | : | Equipped |
|  | (4) | The control unit automatically detects the handpiece | | : | Equipped |
|  | (5) | Foot switch | | : | Equipped |
|  | (6) | Speed and work mode can be footswitch/pedal controlled | | : | Equipped |
|  | (7) | Irrigation/suction capacity | | : | 2000 ml/min |
| **3.QUALITY ASSURANCE REQUIREMENTS** | | | | | |
|  | (1) | EC Certification | |  |  |
|  | (2) | Manufacturer ISO 13485 | |  |  |
|  | (3) | Declaration of conformity with guideline 93/42/EEC | |  |  |
|  | (4) | Warranty at least 12 months | |  |  |
| **4.SPARE PARTS** | | | | | |
| 4-1 Not required | | | | | |
| **5. CONSUMABLES** | | | | | |
| 5-1Suction tube | | | | : | 5 sets |
| 5-2 In and outflow tubing for irrigation | | | | : | 5 sets |
| **6. NOTE** | | | | | |
| Equipment assembly, installation and commissioning on site at beneficiary location | | | | | |
| User’s manuals, preferable in Romanian or Russian language (optional English) | | | | | |
| Maintenance manual, preferable in Romanian or Russian language (optional English) | | | | | |
| Compatible with arthroscope (same manufacturer) | | | | | |