**Annex 1**

**Technical Specifications**

**Lot 1:**

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| **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**

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| **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**

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| **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**

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| **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**

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| **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) |