**Annex 1**

**Technical Specifications**

**Lot 1: Arhroscope and Suction-irrigation unit/ same manufacturer/ compatible devices**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Arthroscope** | | | | | **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 suction-irrigation unit (same manufacturer)** | | | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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)** | | | | | |