**Annex 4**

|  |  |
| --- | --- |
|  |  **Steam Sterilizer (Autoclave)** |
|  | **Detailed technical description** | **Bidder’s specifications** |
| Purpose: | Designed for total elimination and/or inactivation of microorganisms from medical devices and related products using hot  |  |
|  **1. Composition** *(please specify)* |
| **1.1** | **Composition** |  |  |  |  |  |  |  |  |  |  |
|  1. Sterilizer
 |  |
| **1.2** | **Accessories** |  |  |  |  |  |  |  |  |  |  |
| Any other accessory which is required for installation and operation should be included and described on your offered specification |  |
| **2. Specifications** *(please indicate the exact specifications)* |
| **2.1 General** |  |
| ─ | Capacity approx. 120L to 150L  |  |
| ─ | Horizontal loading, 1 door |  |
| ─ | Sterilization procedure: steam |  |
| ─ | Microprocessor controlled |  |
| ─ | Forced ventilation |  |
| ─ | Interior chamber made of stainless steel AISI type 304 |  |
| ─ | Temperature adjustment ± 1 °C |  |
| ─ | Timer step ± 1 min |  |
| ─ | Digital display for temperature and time parameters  |  |
| ─ | Overheating protection |  |
| ─ | Alarms: sound, visual (for low pressure and electric system failure or more) |  |
| ─ | Temperature deviation ≤ 2 ° C |  |
| ─ | Programmable sterilization time - up to 120min |  |
| ─ | ≥ 2 shelves, adjustable, stainless steel |  |
| ─ | Monitored parameters: Pressure, Temperature |  |
| ─ | Maximal temperature - up to 134 ° C |  |
| **2.2 Program requirements** |  |
| ─ | 2 Vaccum steps |  |
| ─ | Rubber (121 ° C,125° C) |  |
| ─ | Surgical Instruments (134 ° C) |  |
| ─ | Textiles (134 ° C) |  |
| ─ | Bowie-Dick Test |  |
| ─ | Leakage Test |  |
| ─ | Unwrapped 134 |  |
| ─ | Wrapped 134 |  |
| ─ | Unwrapped 121 |  |
| ─ | Wrapped 121 |  |
| **2.3** | **Display** |  |
| ─ | Color, Touch-screen |  |
| **2.4** | **Printer** |  |
| ─ | Thermal, built-in |  |
| **2.5** | **Power requirements** |  |
| ─ | Power supply 220V AC, 50 Hz |  |
|  **3. General Requirements** *(Mark with yes/ no)* |
| ─ | Compliant to EU Medical Device Directives or US FDA Regulations  |  |
| ─ | Manufacturer ISO 13485 |  |
| ─ | Warranty period at least 2 years |  |
| ─ | Equipment assembly, installation and commissioning on site at beneficiary location |  |
|  **4. Training** *(Mark with yes/ no)* |
| ─ | Training for all medical personnel who will be using this item, on each individual site |  |
| ─ | Training in Romanian or Russian language |  |
| **5. Documentation** *(Indicate manuals’ language)* |
| ─ | User’s manuals, preferable in Romanian or Russian language (optional English) |  |
| ─ | Maintenance manual, preferable in Romanian or Russian language (optional English) |  |
|  **6. Consumables** *(Mark with yes/ no)* |
| ─ | No |   |   |   |   |   |   |   |   |   |   |   |  |