**Annex 4**

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|  | | **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 |  |  |  |  |  |  |  |  |  |  |  |  |