#### TECHNICAL COMPLIANCE MATRIX

**Req. 134349 for Morocco**

Please complete Technical Compliance Matrix.

Instructions for Completing the Compliance Matrix:

1. Bidders must provide a detailed response for each specification line item, including specific technical details of the proposed solution. Responses should not simply repeat the provided specifications. In case of non-compliance with one of the required specifications due to different technology, justification and scientific and clinical evidence shall be provided for evaluation.

2. If referencing a technical proposal, bidders must clearly indicate where the relevant information can be found.

3. Generic statements such as “we shall customize to your needs/requirements” are unacceptable and will not be considered.

| **Ref.** | **Specification Requirements** | **Compliance Yes/No** | **Bidder’s comments** |
| --- | --- | --- | --- |
| **2.1** | **General characteristics** |  |  |
| Double Loop technology for optimum cycles | Yes  No |  |
| Closed circuit operation – Catalytic filter in case of CTA failure | Yes  No |  |
| Proprietary HMI color touch screen | Yes  No |  |
| GAMP compliant software | Yes  No |  |
| Compact and mobile design | Yes  No |  |
| Easily cleanable surfaces | Yes  No |  |
| Volt free contacts for external communication | Yes  No |  |
| Integrated thermal printer | Yes  No |  |
| Remote Start/Stop with remote screen | Yes  No |  |
| Parameterization and recording of cycles | Yes  No |  |
| Effective against a broad spectrum of microorganisms | Yes  No |  |
| H2O2 sensor | Yes  No |  |
| HR probe | Yes  No |  |
| Decontamination capacity: 100m3\* | Yes  No |  |
| **2.2** | **Technical characteristics** |  |  |
| External materials of construction: compliant to be used in a clean room iso 5 | Yes  No |  |
| Temperature - Operation: 15°C to 30°C | Yes  No |  |
| Power supply / Consumption: AC 220 – 240V 50 Hz (Euro), 6Amp | Yes  No |  |
| Position: Vertical only | Yes  No |  |
| Volume H202 Liquid: 1 Liter | Yes  No |  |
| Concentration H202 Liquid: 30-60% w/w | Yes  No |  |
| Control System: Siemens S7 PLC (GAMP compliant software) | Yes  No |  |
| Air flow - Gassing: 25m3/h  - Aeration: 25m3/h at 800Pa external pressure | Yes  No |  |
| Pressure available at output: 1200Pa | Yes  No |  |
| Output steam temperature: From 50°C to 75°C | Yes  No |  |
| Liquid H202 injection rate: 2 – 8 g/min | Yes  No |  |
| Refrigeration System Temperature: Approx. 2°C | Yes  No |  |
| Condensate Disposal: Evaporation into the atmosphere | Yes  No |  |
| Efficacité filtre HEPA d’entrée : 99.99% | Yes  No |  |
| Efficacité filtre HEPA Circuit A et B : 99.99% | Yes  No |  |
| Pressurisation Système débit d’air : 100 l/min (max) | Yes  No |  |
| Gamme de Pressurisation Système : -70Pa à -10Pa, +10Pa à +70Pa | Yes  No |  |
| Filtres Catalytiques : Charbon | Yes  No |  |
| Capacité de décontamination : Jusqu’à 100m3 | Yes  No |  |
| **2.3** | **Accessories required** |  |  |
| 1. The portable gas leak detector | Yes  No |  |
| 1. Adapter plate for gassing the freeze dryer chamber | Yes  No |  |
| 1. H2O2 PROBE HOLDER on Bioquell L4 generator | Yes  No |  |
| 1. Insulated pipe for gassing | Yes  No |  |
| 1. Return pipe | Yes  No |  |
| 1. 4 Bottle of hydrogen peroxide 35% of 1 Liter | Yes  No |  |
| **3** | **Marking** |  |  |
| 3.1. | The System shall have all safety markings (bar codes; name plates with manufacturer’s name, model number, manufacturing standard, hazard or fragility warnings) in English. | Yes  No |  |
| **4** | **Packing** |  |  |
| 4.1. | The System, for the shipment by air to the End-User, shall be packed in accordance with international standards that are applicable for the shipment by air of this kind of equipment. | Yes  No |  |
| 4.2. | The manufacturer of the system must guarantee that the equipment arrives in optimum state for its later installation. | Yes  No |  |
| **5** | **Quality Requirements** |  |  |
| 5.1. | The System shall be manufactured, shipped and installed in accordance with the Contractor’s ISO quality assurance system or an equivalent quality assurance system. | Yes  No |  |
| 5.2. | The Contractor shall document the compliance with this quality assurance system. | Yes  No |  |
| **6** | **Testing and Acceptance** |  |  |
| 6.1 | The System, prior to shipment, shall be tested for conformance of the System with manufacturer’s performance specifications and the minimum requirements specified herein. | Yes  No |  |
| 6.2 | The System, after installation, shall be tested by the Contractor together with the End-User to demonstrate that the performance meets the manufacturer’s performance specifications and the minimum requirements specified herein as determined by the IAEA and the End-User. | Yes  No |  |
| 6.3 | The results of the testing of the System shall be documented by the Contractor in an acceptance protocol that shall be signed by the End-User. | Yes  No |  |
| **7** | **Installation and Training** |  |  |
| 7.1. | The Contractor shall install and integrate the system in existing freeze dryer unit at the End-User facilities. Integration of the generator in the telstar lyogamma 15-3 freeze dryer before the start of qualification | Yes  No |  |
| 7.2. | Installation Qualification (IQ) and Operational Qualification (QO) of the Generator. The IQ/OQ must include protocols and the execution of functionality tests according to the characteristics of the freeze dryer lyogamma 15-3 (TELSTAR). | Yes  No |  |
| **8** | **Cycle Development** |  |  |
| 8.1. | Identification of the parameters of the "optimum" bio-decontamination cycle (time/efficiency/H2O2 consumption) involving the study of the distribution of the steam, the mapping of the temperature, the quantity of H2O2, the contact times and aeration. | ☐ Yes  ☐ No |  |
| 8.2. | Use of biological indicators at 6log of Geobacillus Stearothermophilus spores to confirm the effectiveness of the process. | ☐ Yes  ☐ No |  |
| **9** | **Operator training in routine operation and maintenance** |  |  |
|  | Training of three operators in the operation and routine maintenance of the generator | ☐ Yes  ☐ No |  |
| **10** | **Deliverable Data Items** |  |  |
|  | The Contractor shall provide two complete sets of operation and servicing manuals and technical drawings in the English/ French. | ☐ Yes  ☐ No |  |