



## SPECIFICATION

### Synthesizer Module for labelling of biomolecules with Ga-68, Lu-177 and Y-90

#### 1. Scope

The purpose of this document is to define the Specifications for a fully automated **Synthesizer Module** (hereinafter referred as “the System”), including on-site installation and training. The System will be used for labelling of biomolecules with Ga-68, Lu-177 and Y-90 by the Nuclear Medicine Tygerberg Hospital and Stellenbosch University, South Africa.

#### 2. Applicable Documents

The following documents shall be applicable for this Specification to the extent specified hereinafter:

European Union Good manufacturing practice (EU GMP):  
[http://ec.europa.eu/health/documents/eudralex/vol-4\\_en](http://ec.europa.eu/health/documents/eudralex/vol-4_en).

In the event of conflict between the documents listed above and the content of this Specification, the content of this Specification shall take precedence to the extent of the conflict.

#### 3. Requirements

##### 3.1. Functional and Performance Requirements

The System shall meet the following functional and performance requirements:

3.1.1. The module shall be able to label biomolecules, e.g., peptides, antibodies, etc., with Ga-68, Lu-177 and Y-90.

3.1.2 Compatible with ITG Ga-68 generator

##### 3.2. Technical Requirements

The System shall meet the following technical requirements:

3.2.1. The module shall be accompanied by with all required accessories.

3.2.2. The module shall be accompanied by with interface cables

3.2.3. The module shall be accompanied by with power rechargers

3.2.4. The module shall be accompanied by with spare kits/ vials, etc.

#### 4. Marking

The System shall have all safety markings in English language.

#### 5. Packing

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.



## 6. Quality Requirements

- 6.1. The System shall be manufactured, shipped and installed in accordance with the Contractor's ISO quality assurance system or an equivalent quality assurance system.
- 6.2. The Contractor shall document the compliance with this quality assurance system as per Contractor's ISO quality assurance system

## 7. Testing and Acceptance

### 7.1. On site Acceptance Test (SAT)

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. SAT shall be performed in presence of a representative of the Contractor, End-User and the IAEA.

- 7.2. The results of the testing of the System shall be documented in full detail by the Contractor in an SAT report that shall be confirmed and signed by the End-User and the Contractor's representative, to be provided to the IAEA. This document shall be dated and accepted as the start of the System's warranty period.

## 8. Installation and Training

- 8.1. On-site installation shall be performed by the Contractor's technicians. The Contractor shall provide all necessary drawings and installation provisions, including photos and other useful information for site preparation. The installation will be accepted after commissioning (SAT), training and validation. The validation will consist of three (3) runs of the installation to validate that the process allows meeting the design specifications and GMP requirements. This step will also be used as training of End-User's staff. The results of the installation and operation of the System shall be documented in full detail by the Contractor in the documentation, to be provided to the IAEA.
- 8.2. The Contractor shall provide at least one day full - training for End-User staff in the operation and application of the System and its components at the End-User location immediately after the installation has been completed. The training shall be held in the English language.

## 9. Deliverable Data Items

The following data items shall be delivered in English. All the necessary drawings and documents relevant to the manufacturing and operation of the System shall be provided by the Contractor to the End-User. The documentation to be provided shall include, but it is not limited to, the following:



- 9.1 Maintenance and User's manual in English
  - 9.2 Technical documentation
  - 9.3 Technical drawings (electrical, mechanical, pneumatic & process schemes)
  - 9.4 Certificates of all used materials
  - 9.5 Signed SAT report
  - 9.6 Recommended spare parts list (included in the maintenance manual)
  - 9.7 Main equipment data sheets
  - 9.8 Instruments calibration certificates
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