Certificate No: **GMP 158/16**

# CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

**Part 1**

**Issued following an inspection in accordance with the requirements of Good Manufacturing Practice, of the Israeli laws and regulations (Pharmacist Regulations [Good Manufacturing Practice for Medicinal Products ] 2008)**

**and**

**Issued under the provisions of the Conformity Assessment and Acceptance of Industrial Products (CAA) Agreement between the European Union and Israel**

The competent authority of Israel confirms the following:

| | |
|---|---|
| **The manufacturer** | **Isotopia Molecular Imaging Ltd.** |
| **Site address** | **Segula Ind. Zone, 39 Alexander Yanai St., Petakh Tikva, 4927735, Israel** |

Has been inspected under the Israeli inspection programme, in connection with manufacturing authorization no. **MIA 158**, in accordance with the above mentioned laws and regulations

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **5-9 January 2025,** it is considered that it complies with the Good Manufacturing Practice requirements referred to in the Conformity Assessment and Acceptance of Industrial Products (CAA) Agreement between the European Union & Israel and the above mentioned Israeli laws & regulations(*).

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than **three years** have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.

This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMP.
If it does not appear, please contact the issuing authority.

(*) these requirements fulfill the GMP recommendations of WHO

MINISTRY OF HEALTH JERUSALEM
GOV. INSTITUTE FOR CONTROL AND STANDARD OF PHARMACEUTICALS
משרד הבריאות

27.10.25

ע. מפקח ארצי
תנאי יצור נאותים



Ministry Of Health, MTIR Directorate
The Institute for Standardization and Control of Pharmaceuticals
9 Ya'akov Eli'av St., Jerusalem, 9546208, Israel
Tel: 972-2-6551717, Fax: 972-2-6551777

משרד הבריאות
חטיבת טכנולוגיות רפואיות, מידע ומחקר
המכון לביקורת ותקינה של חומרי רפואה
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טל: 02-6551717, פקס: 02-6551777

## Part 2 - HUMAN MEDICINAL PRODUCTS

### 1. MANUFACTURING OPERATIONS – MEDICINAL PRODUCTS

1.1 Sterile products

1.1.2 Terminally sterilized

1.1.2.5 Other terminally sterilized prepared products
*(Lutetium-177 sterile radionuclides)*

1.1.3 Batch certification

1.5 Packaging

1.5.2 Secondary packing

1.6 Quality control testing

1.6.1 Microbiological: sterility
*(performed at another site of the firm)*

1.6.2 Microbiological: non-sterility
*(performed at another site of the firm)*

1.6.3 Chemical/Physical
*(the Gamma-ray spectrometry test can also be outsourced)*

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### 2. IMPORTATION OF MEDICINAL PRODUCTS

2.2 Batch certification of imported medicinal products

2.2.1 Sterile Products

2.2.1.1 Aseptically prepared
*(lyophilized powder in glass vial, for diagnostic use)*

2.3 Other importation activities

2.3.1 Site of physical importation : *site of a contract manufacturer*

2.3.4 Others : Radiopharmaceuticals/Radionuclide generators
*(radiopharmaceuticalprecursor, sterile solution)*



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## Part 2 - HUMAN INVESTIGATIONAL MEDICINAL PRODUCTS

### 1. MANUFACTURING OPERATIONS – INVESTIGATIONAL MEDICINAL PRODUCTS

**for phases I , II clinical trials**

1.1 Sterile products

1.1.2 Terminally sterilized

1.1.2.5 Other terminally sterilized prepared products
*(Terbium-161 sterile radionuclides)*

1.1.3 Batch certification

1.5 Packaging

1.5.2 Secondary packing

1.6 Quality control testing

1.6.1 Microbiological: sterility

*(performed at another site of the firm)*

1.6.2 Microbiological: non-sterility

*(performed at another site of the firm)*

*1.6.3* Chemical/Physical

*(the Gamma-ray spectrometry test can also be outsourced)*

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**Any restrictions or clarifying remarks related to the scope of this certificate**

▶ *The commercial products are Lutetium-177 carrier added & Lutetium-177 non carrier added, sterile radionuclides.*
▶ *The IMP is Terbium-161 sterile radionuclide. It is manufactured in a dedicated room (# 23). This activity as authorized after an "inspection for cause" that was conducted on 3 June 2025. The authorization is valid for phases I , II clinical trials.*

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|---|
| *IMPs for phase III clinical studies are periodically inspected and approved under the national inspecti programme* |
| *IMPs for phases I, II, are not inspected under this programme. Their production is permitted after ensuring that they do not pose risk of contamination to other products.* |
| *IMPs are not included in the ACAA between the EU and Israel* |

**Name and signature of the authorized person of the Competent Authority of Israel**

Michael Carmi, Pharmacist, GMP Inspector

*Email: michael.carmi@moh.gov.il*
*Phone: office 972 -2-6551795, cell 972-50-6242452*

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