Certificate No: **GMP 158/5**

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	**39 Alexander Yanay St., Segula Ind. Zone, Petach Tikva, 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

and

is an active substance manufacturer that has been inspected in accordance with the ICH Q7 guideline

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **25-27 August, 17 December 2019**, 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 and Israel and the above mentioned Israeli laws and 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 **after the last day of December 2022** (three years since 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

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ת.ד. 34410, ירושלים 9134302
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Part 2

HUMAN MEDICINAL PRODUCTS

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance(s): *Lutetium 177, a sterile radioactive API*

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.3 Salt formation / Purification steps : *formation of chloride salt, separation and elusion*

3.1.4 Other : *bioburden reduction by filtration*

3.4 Manufacture of sterile active substance

3.4.2 Terminally sterilized

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.5.4 Other : Batch release

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing - non sterility *(performed at another site of the firm)*

3.6.3 Microbiological testing - sterility *(performed at another site of the firm)*

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

None

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

Michael Carmi, Pharmacist, GMP Inspector

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

04 -02- 2020

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