

Certificate No: **GDP 158/1**

CERTIFICATE OF GDP COMPLIANCE OF A WHOLESALE DISTRIBUTOR
issued following an inspection in accordance to The Pharmacists Regulations

The competent authority of Israel confirms the following:

The wholesale distributor

Isotopia Molecular Imaging Ltd.

Site address

39 Alexander Yanay St., Segula Ind. Zone, Petach Tikva, 4927735, Israel

Has been inspected under the national inspection programme

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on **23-26 May 2021**, it is considered that it complies with the Good Distribution Practice requirements laid down in Article 1 of Pharmacists Regulations (GMP 2008).

This certificate reflects the status of the premises 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, by 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.

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

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

Michael Carmi, Pharmacist, GMP Inspector

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ANNEX 1

Name and address of the site

Isotopia Molecular Imaging Ltd.

39 Alexander Yanay St., Segula Ind. Zone, Petach Tikva, 4927735, Israel

1. MEDICINAL PRODUCTS

- 1.1 with a Marketing Authorization in Israel (*imported products*)
- 1.2 without a Marketing Authorization in Israel and intended for Israel
- 1.3 with a Marketing Authorization in Israel and intended for exportation
- 1.4 without a Marketing Authorization in Israel and intended for exportation (*Lutetium-177*)

2. AUTHORIZED WHOLESALE DISTRIBUTION OPERATIONS

- 2.1 Procurement
- 2.2 Holding
- 2.3 Supply
- 2.4 Export (*of Lutetium-177 only*) (*)
- 2.5 Other activities(s):

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

- 3.1 Special Products
 - 3.1.1 Narcotic or psychotropic products
 - 3.1.2 Medicinal products derived from blood
 - 3.1.3 Immunological medicinal products
 - 3.1.4 Radiopharmaceuticals (including radionuclide kits)
- 3.2 Medicinal gases
- 3.3 Cold chain products (requiring low temperature handling)
- 3.4 Other products: API (*Lutetium-177*) (*)

(*) see Annex 5 for clarification



ANNEX 2

Contract Wholesale Distribution sites

None


15-12-2021


ANNEX 3

Name(s) of responsible person(s)

As stated in the firm's license (MIA, Manufacturer's / Importer's Authorization)



ANNEX 4

Date of Inspection, on which authorization was granted

23-26 May 2021

GDP certificate was issued for the first time after this inspection

15-12-2021

ANNEX 5

Additional provisions

(*) The only product that the firm manufactures, stores on site, distributes in Israel and exports, is Lutetium-177 (carrier added & non carrier added), a sterile radionuclide. This product is defined as a medicinal product in Europe, and as an API in the US. The product is in the process of being registered in Israel.

The other products that the firm handles are imported and stored at a contract manufacturer's warehouse. They are distributed in Israel and not intended for export.



15-12-2021