



אישור יצרן / יבואן תכשירים רפואיים
MANUFACTURER'S / IMPORTER'S AUTHORIZATION

Authorization number	מספר האישור
MIA 158/2025/D	
Name of authorization holder	שם בעל האישור
Isotopia Molecular Imaging Ltd.	איזוטופיה מולקולר אימג'ינג בע"מ
Address of site	כתובת האתר
Segula Ind. Zone, 39 Alexander Yanai St., Petakh Tikva, 4927735, Israel	א.ת. סגולה, רח' אלכסנדר ינאי 39, פתח תקווה 4927735
Legally registered address of authorization holder	כתובת בעל האישור
As written above	כרשום לעיל
Scope of authorization and dosage forms	תחומי האישור וצורות המינון
See Annexes 1, 2	ראה נספחים 1, 2
Legal basis of authorization	הבסיס החוקי לאישור
Pharmacist Regulations [Good Manufacturing Practice] 2008	תקנות הרוקחים [תנאי ייצור נאותים] תשס"ח
Responsible officer of Israeli Ministry Of Health granting the authorization	בעל התפקיד ברשות האחראי למתן האישור
Michael Carmi, Pharmacist GMP inspector	מיכאל כרמי, רוקח רכז ארצי בקרת מפעלים
Signature, stamp and date	חתימה, חותמת ותאריך
<i>e-mail: michael.carmi@moh.gov.il phone: office 972 -2-6551795 cell 972-50-6242452</i>	 27.10.25 מיכאל כרמי: ע. מפקח ארצי תנאי ייצור נאותים
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SCOPE OF AUTHORIZATION : ANNEX 1 – MEDICINAL PRODUCTS

Name and address of the site **Isotopia Molecular Imaging Ltd.**
Segula Ind. Zone, 39 Alexander Yanai St., Petakh Tikva, 4927735, Israel

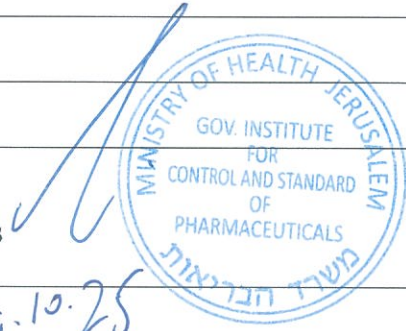
Human Medicinal Products

AUTHORIZED OPERATIONS

Manufacturing Operations (according to part 1)

Importation of Medicinal Products (according to part 2)

Part 1 - MANUFACTURING OPERATIONS	
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)



מיכאל כרמי
ע. מפקח ארצי
חנאי יצור נאותים

Any restrictions or clarifying remarks related to the scope of these manufacturing operations

The commercial products are Lutetium-177 carrier added & Lutetium-177 non carrier added, sterile radionuclides



Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.2	Batch certification of imported medicinal products
	2.2.1 Sterile Products
	2.2.1.1 Aseptically prepared (<i>lyophilized powder in glass vial, for diagnostic use</i>)
2.3	Other importation activities
	2.3.1 Site of physical importation : <i>site of a contract manufacturer</i>
	2.3.4 Others: Radiopharmaceuticals/Radionuclide generators (<i>radiopharmaceutical precursor, sterile solution</i>):

Any restrictions or clarifying remarks related to the scope of these importing operations:

The imported products are stored at a contract manufacturer's warehouse

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27.10.25

מיכאל כרמי
ע. מפקח ארצי
תגאי יצור נאותים



SCOPE OF AUTHORIZATION: ANNEX 2 - INVESTIGATIONAL MEDICINAL PRODUCTS

Name and address of the site **Isotopia Molecular Imaging Ltd.**
Segula Ind. Zone, 39 Alexander Yanai St., Petakh Tikva, 4927735, Israel

<input checked="" type="checkbox"/>	Human Investigational Medicinal Products	<i>for phases I, II clinical trials</i>
AUTHORIZED OPERATIONS		
<input checked="" type="checkbox"/>	Manufacturing Operations (according to part 1)	
Part 1 - MANUFACTURING OPERATIONS		
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 (<i>performed at another site of the firm</i>)	
	1.6.2 Microbiological: non-sterility (<i>performed at another site of the firm</i>)	
	1.6.3 Chemical/Physical (<i>the Gamma-ray spectrometry test can also be outsourced</i>)	

Handwritten signature
 27.10.25
 מיכאל כרמי
 ע. מפקח ארצי
 תנאי יצור נאותים

Any restrictions or clarifying remarks related to the scope of these manufacturing operations

The IMP is Terbium-161 sterile radionuclide. It is manufactured in a dedicated room (# 23). This activity was authorized after an "inspection for cause" that was conducted on 3 June 2025. The authorization is valid for phases I, II clinical trials

IMPs for phase III clinical studies are periodically inspected and approved under the national inspection 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