

Institute For Standardization And Control Of Pharmaceuticals

CERTIFICATE NUMBER: 239/3

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued under the provisions of the Agreement on Conformity Assessment and Acceptance of industrial products (ACAA) between the European Union and *Israel*

The competent authority of Israel confirms the following:

The manufacturer: *S.R.Y. (Medical Services) Ltd.*

Site address: *1, Kalman Man St, Jerusalem, 9112001, Israel*

OMS Organisation Id. / OMS Location Id.: *ORG-100040843 / LOC-100067201*

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on *2023-02-15* , it is considered that it complies with

The Good Manufacturing Practice requirements referred to in the Agreement on Conformity Assessment and Acceptance of industrial products (ACAA) between the European Union and *Israel*

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. 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 EudraGMDP. If it does not appear, please contact the issuing authority.



09-05-2023

מיכאל כרמי
ע. מפקח ארצי
הנאי יצור נאותים

Part 2

Human Medicinal Products	
1 MANUFACTURING OPERATIONS	
1.1	Sterile products
	<i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i> 1.1.1.4 Small volume liquids
	<i>1.1.3 Batch certification</i>
1.5	Packaging
	<i>1.5.1 Primary Packaging</i> 1.5.1.6 Liquids for internal use
	<i>1.5.2 Secondary packaging</i>
1.6	Quality control testing
	<i>1.6.1 Microbiological: sterility</i> <i>1.6.3 Chemical/Physical</i>

Clarifying remarks (for public users)

This certificate is relevant to 177Lu-DOTA-TATE (LuNET- SRY), a Radiopharmaceutical for cancer therapy ; The chemical / physical testing includes LAL.

2023-05-09



מיכאל כרמי
ע. מפקח ארצי
תנאי יצור נאותים

09-05-2023

Name and signature of the authorised person of the Competent Authority of

Michael Carmi

Tel:
Fax: