NATIONAL CENTER FOR PUBLIC HEALTH AND PHARMACY

Directorate for Drug Inspection

National Center For Public Health And Pharmacy

CERTIFICATE NUMBER: *NNGYK/GYSZ/28972-7/2024*

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

Issued following an inspection in accordance with
Art. 111(5) of Directive 2001/83/EC as amended
Art. 15 of Directive 2001/20/EC as amended

The competent authority of Hungary confirms the following:
The manufacturer: ***Medi-Radiopharma Kft.***
Site address: ***Szamos Utca 10-12, Erd, 2030, Hungary, GPS: 47.382994, 18.929235***
OMS Organisation Id. / OMS Location Id.: ***ORG-100000052 / LOC-100001115***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***HU-M-MEDI*** in accordance with Art. 13 of Directive 2001/20/EC and Art. 40 of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2024-06-06***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC[3]

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. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). 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.

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[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/EC and Art. 15 of Directive 2001/20/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.2 Lyophilisates Special Requirements 5 Radiopharmaceuticals 1.1.1.4 Small volume liquids Special Requirements 5 Radiopharmaceuticals 1.1.1.6 Other: Technetium diagnostic kits(en) Special Requirements 5 Radiopharmaceuticals
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids Special Requirements 5 Radiopharmaceuticals 1.1.2.5 Other: Technetium diagnostic kits(en) Special Requirements 5 Radiopharmaceuticals
	1.1.3 Batch certification
1.5	**Packaging**
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

Any restrictions related to the scope of this certificate:

Clarifying remarks (for registered users)

All manufacturing activities listed in this certificate are applicable to Human Medicinal Products including Investigational Medicinal Products.

Clarifying remarks (for public users)

All manufacturing activities listed in this certificate are applicable to Human Medicinal Products including Investigational Medicinal Products.

2024-09-05

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

Országos Gyógyszerészeti és Élelmezés-egészségügyi Központ

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