Health And Youth Care Inspectorate

CERTIFICATE NUMBER: ***NL/H 23/2044028B***

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

Part 1

Issued following an inspection in accordance with :
Art. 63 of Regulation (EU) 536/2014

The competent authority of Netherlands confirms the following:
The manufacturer: ***Universitair Medisch Centrum Groningen***
Site address: ***Hanzeplein 1, Groningen, 9713 GZ, Netherlands, GPS: 53.220613, 6.576401***
OMS Organisation Id. / OMS Location Id.: ***ORG-100022118 / LOC-100030831***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***108964 F*** in accordance with Art. 61 of Regulation (EU) No 536/2014.

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

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and Commission Delegated Regulation (EU) 2017/1569 [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. 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.

---

[1] *The certificate referred to in paragraph Art. 15 of Directive 2001/20/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

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

MC

Part 2

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.4 Small volume liquids Special Requirements 5 Radiopharmaceuticals
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.6 Liquids for internal use Special Requirements 5 Radiopharmaceuticals
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.6 Liquids for internal use Special Requirements 5 Radiopharmaceuticals
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical* *1.6.4 Biological*

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.3	**Other importation activities**
	2.3.1 Site of physical importation
	2.3.2 Importation of intermediate which undergoes further processing

MC

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC testing	Products
Unit 32 and 33	*Nuclear Medicine and Molecular Imaging*	*N/A*	*N/A*	*N/A*

Ad 2.3.2: radiopharmaceutical intermediate products

Clarifying remarks (for public users)

Ad 2.3.2: radiopharmaceutical intermediate products This document also encompasses CTD IMP's

2023-09-08

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

i.a.

Kai Liang
Tel:*+31 881205 000*
Fax: *+31 881205 001*