Health And Youth Care Inspectorate

CERTIFICATE NUMBER: ***NL/H 25/2057675A***

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 as amended

The competent authority of Netherlands confirms the following:
The manufacturer: ***Universitair Medisch Centrum Groningen***
Site address: ***Hanzeplein 1, Groningen, 9713 GZ, Netherlands***
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, transposed in the following national legislation:Art. 100 of the Medicines Act.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2025-09-11***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2. [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. 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 Investigational Medicinal Products

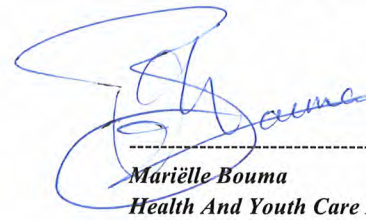
1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.4 Small volume liquids
	1.1.3 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.4 Gene therapy products 1.3.1.5 Biotechnology products 1.3.1.7 Tissue engineered products
	1.3.2 Batch Certification (list of product types) 1.3.2.4 Gene therapy products 1.3.2.5 Biotechnology products 1.3.2.7 Tissue engineered products
1.5	**Packaging**
	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*

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC testing	Products
Unit 50	***unit Biotech and ATMP***	***N/A***	***N/A***	***N/A***

2025-11-11

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



Mariëlle Bouma
Health And Youth Care Inspectorate
Tel:
Fax:

Health And Youth Care Inspectorate

CERTIFICATE NUMBER: ***NL/H 25/2057675B***

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

Part 1

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Site address: ***Hanzeplein 1, Groningen, 9713 GZ, Netherlands***
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From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2025-09-11***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2. [3]

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

Part 2

Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.4 Small volume liquids Special Requirements 5 Radiopharmaceuticals
	1.1.3 Batch certification
1.5	**Packaging**
	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

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***

Clarifying remarks (for registered users)

Ad 2.3.2: radiopharmaceutical intermediate products

Clarifying remarks (for public users)

Ad 2.3.2: radiopharmaceutical intermediate products

2025-11-11

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

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Mariëlle Bouma
Health And Youth Care Inspectorate
Tel:
Fax:

Health And Youth Care Inspectorate

CERTIFICATE NUMBER: ***NL/H 25/2057675C***

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

Part 1

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Part 2

Human Investigational Medicinal Products

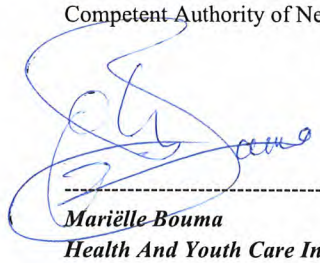
1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.2 Batch Certification (list of product types) 1.3.2.1 Blood products 1.3.2.2 Immunological products 1.3.2.3 Cell therapy products 1.3.2.4 Gene therapy products 1.3.2.5 Biotechnology products 1.3.2.7 Tissue engineered products
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.2 Capsules, soft shell 1.5.1.8 Other solid dosage forms 1.5.1.13 Tablets 1.5.1.14 Transdermal patches
	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*

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC testing	Products
Unit 50	***Clinical Pharmacy & Pharmacology (KFF)***	***N/A***	***N/A***	***N/A***

2025-11-11

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



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