Inspectie Gezondheidszorg en Jeugd
Ministerie van Volksgezondheid,
Welzijn en Sport

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AANGETEKEND
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Farmaceutische Producten
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Ons kenmerk
V2029320

Datum 27-05-2022
Onderwerp Certificaatnummers NL/H21/2029320A + NL/H21/2029320B + NL/H21/2029320C

☐ Met het verzoek om advies

☐ Naar aanleiding van uw brief

☐ Ter kennisneming

☒ Zoals aangevraagd

☐ Met het verzoek voor verdere behandeling zorg te dragen

☐ Met dank voor inzage

☐ Om te behouden

Met vriendelijke groet,

Jeroen van Iersel
Medewerker Toezicht IGJ
.....
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Duidelijk. Onafhankelijk. Eerlijk.
.....

Health and Youth Care Inspectorate – Pharmaceutical Products

CERTIFICATE NUMBER: ***NL/H 21/2029320A***

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

Part 1

Issued following an inspection in accordance with :
Art. 15 of Directive 2001/20/EC

The competent authority of Netherlands confirms the following:
The manufacturer: ***Leiden University Medical Center***
Site address: ***Albinusdreef 2, Leiden, 2333 ZA, Netherlands***
OMS Location: ***LOC-100019974***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***4576 F*** in accordance with Art. 13 of Directive 2001/20/EC 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 ***2021-09-30***, 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. 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/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.*

Part 2

Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.1 Large volume liquids 1.1.2.3 Small volume liquids
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.5 Liquids for external use 1.2.1.6 Liquids for internal use 1.2.1.11 Semi-solids 1.2.1.12 Suppositories 1.2.1.13 Tablets
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.8 Other solid dosage forms 1.5.1.11 Semi-solids 1.5.1.12 Suppositories 1.5.1.13 Tablets
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical* *1.6.4 Biological*

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.2 Microbiological: non-sterility *2.1.3 Chemical/Physical* *2.1.4 Biological*
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	2.2.2 Non-sterile products
	2.2.3 Biological medicinal products 2.2.3.1 Blood products 2.2.3.2 Immunological products 2.2.3.3 Cell therapy products 2.2.3.4 Gene therapy products 2.2.3.5 Biotechnology products 2.2.3.6 Human or animal extracted products
2.3	**Other importation activities**
	2.3.2 Importation of intermediate which undergoes further processing

Any restrictions related to the scope of thiscertificate:

This certificate relates to the activities performed at location L0. The name of the legal entity is: Academisch Ziekenhuis Leiden.

Clarifying remarks (for public users)

This certificate relates to the activities performed at location L0. The name of the legal entity is: Academisch Ziekenhuis Leiden.

2022-05-02

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

Ms. Mieke van der Meulen
Health and Youth Care Inspectorate – Pharmaceutical Products
Tel:***+31 88 1205000***
Fax:***+31 88 1205001***

Health and Youth Care Inspectorate – Pharmaceutical Products

CERTIFICATE NUMBER: ***NL/H 21/2029320B***

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

Part 1

Issued following an inspection in accordance with :
Art. 15 of Directive 2001/20/EC

The competent authority of Netherlands confirms the following:
The manufacturer: ***Leiden University Medical Center***
Site address: ***Albinusdreef 2, Leiden, 2333 ZA, Netherlands***
OMS Location: ***LOC-100019974***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***4576 F*** in accordance with Art. 13 of Directive 2001/20/EC 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 ***2021-09-30***, 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. 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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[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) 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids 1.1.1.6 Other: ATMPs(en)
	1.1.3 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.3 Cell therapy products 1.3.1.4 Gene therapy products 1.3.1.7 Tissue engineered products
	1.3.2 Batch Certification (list of product types) 1.3.2.3 Cell therapy products 1.3.2.4 Gene therapy products 1.3.2.7 Tissue engineered products
1.4	**Other products or manufacturing activity**
	1.4.2 Sterilisation of active substance/ excipients/ finished product 1.4.2.1 Filtration
1.6	**Quality control testing**
	1.6.3 Chemical/Physical *1.6.4 Biological*

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.2	**Batch certification of imported medicinal products**
	2.2.3 Biological medicinal products 2.2.3.7 Tissue engineered products

Any restrictions related to the scope of thiscertificate:

This certificate relates to the activities performed at location J10. The name of the legal entity is: Academisch Ziekenhuis Leiden.

Clarifying remarks (for public users)

This certificate relates to the activities performed at location J10. The name of the legal entity is: Academisch Ziekenhuis Leiden.

2022-05-02

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

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Ms. Mieke van der Meulen
Health and Youth Care Inspectorate – Pharmaceutical Products
Tel:***+31 88 1205000***
Fax:***+31 88 1205001***

Health and Youth Care Inspectorate – Pharmaceutical Products

CERTIFICATE NUMBER: ***NL/H 21/2029320C***

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

Part 1

Issued following an inspection in accordance with :
Art. 15 of Directive 2001/20/EC

The competent authority of Netherlands confirms the following:
The manufacturer: ***Leiden University Medical Center***
Site address: ***Albinusdreef 2, Leiden, 2333 ZA, Netherlands***
OMS Location: ***LOC-100019974***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***4576 F*** in accordance with Art. 13 of Directive 2001/20/EC 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 ***2021-09-30***, 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. 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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[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.*

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**
	1.6.3 Chemical/Physical

Any restrictions related to the scope of thiscertificate:

This certificate relates to the activities performed at location C0. The name of the legal entity is: Academisch Ziekenhuis Leiden.

Clarifying remarks (for public users)

This certificate relates to the activities performed at location C0. The name of the legal entity is: Academisch Ziekenhuis Leiden.

2022-05-02

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

Ms. Mieke van der Meulen
Health and Youth Care Inspectorate – Pharmaceutical Products
Tel:***+31 88 1205000***
Fax:***+31 88 1205001***