

## Swedish Medical Products Agency

CERTIFICATE NUMBER: **SE-HI-GMP-24-021843**

# CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER<sup>1,2</sup>

### Part 1

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

The competent authority of Sweden confirms the following:

The manufacturer: **ClinStorage AB**

Site address: **Vastbergavagen 41, Brannkyrka, Hagersten, 126 30, Sweden, GPS: 59.289777, 18.010185**

OMS Organisation Id. / OMS Location Id.: **ORG-100019155 / LOC-100089427**

Has been inspected under the national inspection programme in connection with manufacturing  
authorisation no. **SE-HI-MIA-24-021843** 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 **2024-09-05**, 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.<sup>3</sup>

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.

<sup>1</sup>The certificate referred to in paragraph Art. 15 of Directive 2001/20/EC is also applicable to importers.

<sup>2</sup>Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.

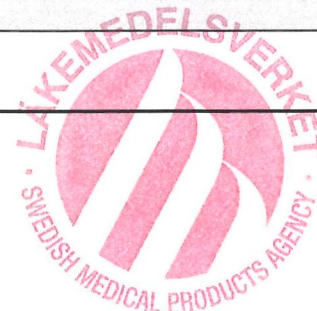
<sup>3</sup>These requirements fulfil the GMP recommendations of WHO.



**Part 2**

Human Investigational Medicinal Products	
<b>1 MANUFACTURING OPERATIONS</b>	
<b>1.1</b>	<b>Sterile products</b>
	<i>1.1.3 Batch certification</i>
<b>1.2</b>	<b>Non-sterile products</b>
	<i>1.2.2 Batch certification</i>
<b>1.3</b>	<b>Biological medicinal products (list of product types)</b>
	<i>1.3.1 Biological medicinal products (list of product types)</i> 1.3.1.5 Biotechnology products
	<i>1.3.2 Batch Certification (list of product types)</i> 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
<b>1.5</b>	<b>Packaging</b>
	<i>1.5.2 Secondary packaging</i>

<b>2 IMPORTATION OF MEDICINAL PRODUCTS</b>	
<b>2.2</b>	<b>Batch certification of imported medicinal products</b>
	<i>2.2.1 Sterile products</i> 2.2.1.1 Aseptically prepared
	<i>2.2.2 Non-sterile products</i>
	<i>2.2.3 Biological medicinal products</i> 2.2.3.5 Biotechnology products
<b>2.3</b>	<b>Other importation activities</b>
	<i>2.3.1 Site of physical importation</i>



Clarifying remarks (for public users)

**1.3.1.5 Storage of master cell banks and working cell banks. 1.5.2 Secondary packaging includes blinded, randomised packaging and labelling.**

2024-11-14



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

*Bengt Berglund*

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