

Medical Products Agency

CERTIFICATE NUMBER : **5.9.1-2022-004613**

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 Sweden confirms the following:

The manufacturer : ***Clinstorage AB***

Site address : ***Banvaktsvagen 22, Solna, 171 48, Sweden***

OMS Location : ***LOC-100027916***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **5.9.1-2022-004613** in accordance with Art. 61 of Regulation (EU) 536/2014 .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2021-04-14** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC³

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.



Part 2

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

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

2022-03-16

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



Mr. Bengt Berglund
Medical Products Agency
Tel :+46 18 174600
Fax :+46 18 548566

