National Authority Of Medicines And Health Products

CERTIFICATE NUMBER: ***F066/S1/ME/001/2021***

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 Portugal confirms the following:
The manufacturer: ***Stemlab S.A.***
Site address: ***Lote 3 Nucleo 4, Parque Tecnologico De, Cantanhede, 3060-197, Portugal***
OMS Organisation Id. / OMS Location Id.: ***ORG-100018883*** / ***LOC-100027665***

Has been inspected under the national inspection programme in accordance with Art. 13 of Directive 2001/20/EC transposed in the following national legislation:
Art. 29 of Law n. º 46/2004, de 19 of August

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2021-01-22***, 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. 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.*

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Part 2

Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
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 Special Requirements 7 Other: Cell therapy products(en) 1.3.1.7 Tissue engineered products
	1.3.2 Batch Certification (list of product types) 1.3.2.3 Cell therapy products Special Requirements 7 Other: Cell therapy products(en) 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*

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Any restrictions related to the scope of this certificate:

- Restricted to the production of ATIMP Stemlab_CD34BM, for clinical trial EudraCT N.º 2017-002456-88, and supply to the investigational site Centro Hospitalar e Universitário de Coimbra, E.P.E. - Restricted to the production of: Investigational ATMP SLCTmsc02, Allogeneic cord tissue-derived mesenchymal stromal cells ex-vivo expanded suspension for injection. - Based on the outcome of the inspection performed from 11th to 12th of January 2024, and in order to conclude the inspection process, this GMP certificate is valid until 30th June 2024.

Clarifying remarks (for public users)

- Restricted to the production of ATIMP for clinical trial EudraCT N.º 2017-002456-88. - Restricted to the production of: Investigational ATMP SLCTmsc02, Allogeneic cord tissue-derived mesenchymal stromal cells ex-vivo expanded suspension for injection. - Based on the outcome of the inspection performed from 11th to 12th of January 2024, and in order to conclude the inspection process, this GMP certificate is valid until 30th June 2024.

2024-02-07

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

Maria Fernanda Ralha

Assinado de forma digital por Maria Fernanda Ralha
Dados: 2024.02.08 10:43:38 Z

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