REPÚBLICA PORTUGUESA
SAÚDE

Infarmed
Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.

Manufacturer/Importer Authorisation [1, 2]

1. Authorisation Number	F066/001/2025
2. Name of authorisation holder	Stemlab S.A. (ORG-100018883 / LOC-100091740)
3. Address(es) of manufacturing site(s)	Stemlab S.A. (ORG-100018883 / LOC-100027665), Lote 3 Nucleo 4, Parque Tecnologico De, Cantanhede, 3060-197, Portugal
4. Legally registered address of authorisation holder	Biocant Park, Nucleo 4 Lote 2, Cantanhede, 3060-197, Portugal
5. Scope of authorisation and dosage forms[2]	ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation	Art. 13 of Directive 2001/20/EC
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Maria Fernanda Ralha Henriques Matos
8. Signature	Maria Fernanda Ralha Assinado de forma digital por Maria Fernanda Ralha Dados: 2025.03.05 10:37:27 Z
9. Date	2024-07-05
10. Annexes attached	Annex 1 and/or Annex 2 Optional Annexes as required: Annex 3(Addresses of Contract Manufacturing Site(s)) Annex 4(Addresses of Contract laboratories) Annex 5(Name of Qualified Person) Annex 6(Name of responsible persons) Annex 7(Date of inspection on which authorisation granted, scope of last inspection) Annex 8(Manufactured/ imported products authorised)[3]

[1] *The authorisation referred to in paragraph 40(1) of Directive 2001/83/EC as amended and Article 88(1) of Regulation (EU) 2019/6, 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 Interpretation of the Union format for Manufacturer/Importer Authorisation.*

[3] *The Competent Authority is responsible for the appropriate linking of the authorisation with the manufacturer's application (Article 42(3) of Directive 2001/83/EC as amended and Article 90(3) of Regulation (EU) 2019/6).*

SCOPE OF AUTHORISATION **ANNEX 2**

Name and address of the site : Stemlab S.A., Lote 3 Nucleo 4, Parque Tecnologico De, Cantanhede, 3060-197, Portugal

Additional Details:

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 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

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

- 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.

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations (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.