

## Manufacturer/Importer Authorisation<sup>1, 2</sup>

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| 1. Authorisation Number  | F063/001/2025   |
| 2. Name of authorisation holder  | ADEIM-Associação Para O Desenvolvimento Do Ensino E Investigação Da Microbiologia (ORG-100034081 / LOC-100080873)   |
| 3. Address(es) of manufacturing site(s)  | ADEIM-Associação Para O Desenvolvimento Do Ensino E Investigação Da Microbiologia (ORG-100034081 / LOC-100080873), Faculdade De Farmácia, Avenida Das Forças Armadas, Lisbon, 1649-019, Portugal  |
| 4. Legally registered address of authorisation holder  | Faculdade De Farmácia, Avenida Das Forças Armadas, Lisbon, 1649-019, Portugal   |
| 5. Scope of authorisation and dosage forms <sup>2</sup>  | ANNEX 1 and/ or ANNEX 2   |
| 6. Legal Basis of authorisation  | Art. 40 of Directive 2001/83/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   |   |
| 9. Date  | 2025-07-28  |
| 10. Annexes attached   | Annex 1 and/or Annex 2<br>Optional Annexes as required:<br>Annex 3(Addresses of Contract Manufacturing Site(s))<br>Annex 4(Addresses of Contract laboratories)<br>Annex 5(Name of Qualified Person)<br>Annex 6(Name of responsible persons)<br>Annex 7(Date of inspection on which authorisation granted, scope of last inspection)<br>Annex 8(Manufactured/ imported products authorised) <sup>3</sup> |

<sup>1</sup>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.

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

<sup>3</sup>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**

Name and address of the site: ADEIM-Associacao Para O Desenvolvimento Do Ensino E Investigacao Da Microbiologia, Faculdade De Farmacia,  
Avenida Das Forcas Armadas, Lisbon, 1649-019, Portugal

Additional Details:

Human Medicinal Products
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<b>Authorised Operations</b>
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MANUFACTURING OPERATIONS(according to part 1)
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<b>Part 1 - MANUFACTURING OPERATIONS</b>
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<b>1.6</b>	<b>Quality control testing</b>
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	<i>1.6.2 Microbiological: non-sterility</i>
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