


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

1. Authorisation Number 2094 IMP
2. Name of authorisation holder Xedev (ORG-100042526 / LOC-100070282)
3. Address(es) of manufacturing site(s) Xedev (ORG-100042526 / LOC-100070282), Poldergotestraat 4, Zele, 9240, Belgium
4. Legally registered address of authorisation holder Poldergotestraat 4, Zele, 9240, Belgium
- 4.a Additional details on units inspected of legally registered address
5. Scope of authorisation and dosage forms<sup>2</sup> ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation Art. 61 of Regulation (EU) No 536/2014
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation Ethel Mertens
8. Signature  On behalf Isabelle Strepenne  
DG Inspection – Head Division Authorisations a.i.
9. Date 2026-02-02
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)<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

ANNEX 2

Name and address of the site : Xedev, Poldergotestraat 4, Zele, 9240, Belgium

Additional Details:

Human Investigational Medicinal Products

### Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

#### Part 1 - MANUFACTURING OPERATIONS

<b>1.2</b>	<b>Non-sterile investigational medicinal products</b>
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.1 Capsules, hard shell 1.2.1.6 Liquids for internal use 1.2.1.8 Other solid dosage forms: powders for further processing(en) 1.2.1.13 Tablets
	<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 1.3.1.8 Other: peptides(en)
	<i>1.3.2 Batch Certification (list of product types)</i> 1.3.2.5 Biotechnology products 1.3.2.8 Other: peptides(en)
<b>1.5</b>	<b>Packaging</b>
	<i>1.5.1 Primary Packaging</i> 1.5.1.1 Capsules, hard shell 1.5.1.6 Liquids for internal use 1.5.1.8 Other solid dosage forms: powders for further processing(en) 1.5.1.13 Tablets

**Any restrictions or clarifying remarks related to the scope of these Manufacturing operations (for Public users)**

1.3.1.5 and 1.3.1.8 limited to formation of powders.