

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

1. Authorisation Number DE\_BW\_01\_MIA\_2024\_0121
2. Name of authorisation holder ATB Pharma Innovation GmbH (ORG-100053060 / LOC-100093609)
3. Address(es) of manufacturing site(s) ATB Pharma Innovation GmbH (ORG-100053060 / LOC-100093609), Kaesenbachstrasse 56, Innenstadt, Tuebingen, Baden-Wuerttemberg, 72076, Germany
- 3.a Additional details on units inspected of manufacturing site(s) address(es)
4. Legally registered address of authorisation holder Kaesenbachstrasse 56, Innenstadt, Tuebingen, Baden-Wuerttemberg, 72076, Germany
- 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 confidential
8. Signature
9. Date 2024-12-18
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).

EudraGMP

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## SCOPE OF AUTHORISATION

## ANNEX 2

Name and address of the site : ATB Pharma Innovation GmbH, Kaesenbachstrasse 56,  
Innenstadt, Tuebingen, Baden-Wuerttemberg, 72076, Germany

Additional Details:

Human Investigational Medicinal Products
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### Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

### Part 1 - MANUFACTURING OPERATIONS

<b>1.1</b>	<b>Sterile products</b>
	<i>1.1.3 Batch certification</i>
<b>1.3</b>	<b>Biological medicinal products (list of product types)</b>
	<i>1.3.2 Batch Certification (list of product types)</i> 1.3.2.4 Gene therapy products 1.3.2.5 Biotechnology products

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

The scope of the authorization in accordance with Annex 2 is limited to the medicinal products specified in Annex 8

### Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

<b>2.2</b>	<b>Batch certification of imported medicinal products</b>
	<i>2.2.1 Sterile products</i> 2.2.1.1 Aseptically prepared
	<i>2.2.3 Biological medicinal products</i> 2.2.3.4 Gene therapy products 2.2.3.5 Biotechnology products

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

The scope of the authorization in accordance with Annex 2 is limited to the medicinal products specified in Annex 8