Manufacturer/Importer Authorisation [1, 2]

1. Authorisation Number	DE_BW_01_MIA_2026_0009
2. Name of authorisation holder	Bioassay Labor fuer biologische Analytik GmbH (ORG-100011526 / LOC-100092934)
2.1. Alternative name of authorisation holder	
3. Address(es) of manufacturing site(s)	Bioassay Labor fuer biologische Analytik GmbH (ORG-100011526 / LOC-100092934), Im Neuenheimer Feld 515, Handschuhsheim, Heidelberg, 69120, Germany Bioassay Labor fuer biologische Analytik GmbH (ORG-100011526 / LOC-100087787), Im Neuenheimer Feld 583, Neuenheim, Heidelberg, 69120, Germany Bioassay Labor fuer biologische Analytik GmbH (ORG-100011526 / LOC-100097990), Im Neuenheimer Feld 517-519, Neuenheim, Heidelberg, 69120, Germany
3.a Additional details on units inspected of manufacturing site(s) address(es)	
4. Legally registered address of authorisation holder	Im Neuenheimer Feld 515, Handschuhsheim, Heidelberg, Baden-Wuerttemberg, 69120, Germany
4.a Additional details on units inspected of legally registered address	
5. Scope of authorisation and dosage forms[2]	ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation	Art. 88 of Regulation (EU) 2019/6
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	confidential
8. Signature	
9. Date	2026-01-28
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]

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[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 1

Name and address of the site: Bioassay Labor fuer biologische Analytik GmbH, Im Neuenheimer Feld 515, Handschuhsheim, Heidelberg, 69120, Germany

Additional Details:

Veterinary Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS(according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.6	**Quality control testing**
	1.6.3 Chemical/Physical *1.6.4 Biological*

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

1.6.3 and 1.6.4 refer to the following test methods: - Potency- Determination Assay of human Choriongonadotropin (HCG) - Potency- Determination Assay of Pregnant Mare Serum Gondotropin (PMSG) - Cell based potency- Determination Assay of hCG (FDH) - Cell-Based Luciferase-Assay for Potency Determination of PMSG - Abnormal toxicity according to Russian Ph. GPM.1.2.4,0004.15

SCOPE OF AUTHORISATION **ANNEX 1**

Name and address of the site: Bioassay Labor fuer biologische Analytik GmbH, Im Neuenheimer Feld 583, Neuenheim, Heidelberg, 69120, Germany

Additional Details:

Veterinary Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS(according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.6	**Quality control testing**
	1.6.3 Chemical/Physical *1.6.4 Biological*

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

1.6.3 and 1.6.4 refer to the following test methods: - Potency- Determination Assay of human Choriongonadotropin (HCG) - Potency- Determination Assay of Pregnant Mare Serum Gondotropin (PMSG) - Cell based potency- Determination Assay of hCG (FDH) - Cell-Based Luciferase-Assay for Potency Determination of PMSG - Abnormal toxicity according to Russian Ph. GPM.1.2.4,0004.15

SCOPE OF AUTHORISATION **ANNEX 1**

Name and address of the site: Bioassay Labor fuer biologische Analytik GmbH, Im Neuenheimer Feld 517-519, Neuenheim, Heidelberg, 69120, Germany

Additional Details:

Veterinary Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS(according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.6	**Quality control testing**
	1.6.3 Chemical/Physical
	1.6.4 Biological

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

1.6.3 and 1.6.4 refer to the following test methods: - Potency- Determination Assay of human Choriongonadotropin (HCG) - Potency- Determination Assay of Pregnant Mare Serum Gondotropin (PMSG) - Cell based potency- Determination Assay of hCG (FDH) - Cell-Based Luciferase-Assay for Potency Determination of PMSG - Abnormal toxicity according to Russian Ph. GPM.1.2.4,0004.15