MANUFACTURER'S AUTHORISATION [1, 2]

1. Authorisation Number	DE_BW_01_MIA_2020_0107
2. Name of authorisation holder	Rentschler Biopharma SE
3. Address(es) of manufacturing site(s)	Rentschler Biopharma SE, Erwin-Rentschler-Strasse 21, Laupheim, Baden-Wuerttemberg, 88471, Germany
4. Legally registered address of authorisation holder	Erwin-Rentschler-Strasse 21, Laupheim, Baden-Wuerttemberg, 88471
5. Scope of authorisation and dosage forms[2]	ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation	Art. 40 of Directive 2001/83/EC Art. 44 of Directive 2001/82/EC Art. 13 of Directive 2001/20/EC
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Friederike Wedelich
8. Signature	
9. Date	2020-11-18
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)[3]

[1] *The authorisation referred to in paragraph 40(1) of Directive 2001/83/EC and 44(1) of Directive 2001/82/EC, as amended, 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 Help menu of EudraGMDP database.*

[3] *The Competent Authority is responsible for appropriate linking of the authorisation with the manufacturer's application (Art. 42(3) of Directive 2001/83/EC and Art. 46(3) of Directive 2001/82/EC as amended).*

SCOPE OF AUTHORISATION **ANNEX 1**

Name and address of the site: Rentschler Biopharma SE, Erwin-Rentschler-Strasse 21, Laupheim, Baden-Wuerttemberg, 88471, Germany

Additional Details:

Human Medicinal Products Veterinary Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS(according to part 1) IMPORTATION OF MEDICINAL PRODUCTS(according to part 2)

Part 1 - MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.3 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.2 Batch Certification (list of product types) 1.3.2.2 Immunological products 1.3.2.5 Biotechnology products
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.3 Other: Active pharmaceutical ingredients, biotechnologically manufactured: recombinant proteins, monoclonal antibodies, cytokines, mRNA-based APIs(en)
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 (for Public users)

ad 1.4.1.3: Authorised manufacturing or importation covers batch certification. According to the facility Layouts, dated September 24, 2020.

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.1 Microbiological: sterility *2.1.2 Microbiological: non-sterility*

	2.1.3 Chemical/Physical *2.1.4 Biological*
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	2.2.3 Biological medicinal products 2.2.3.2 Immunological products 2.2.3.5 Biotechnology products

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

ad 2.2.3.2: recombinant manufactured sera and vaccines ONLY ad 2.2.3.5: Medicinal products, biotechnologically manufactured: recombinant Proteins, monoclonal antibodies, cytokines.

SCOPE OF AUTHORISATION **ANNEX 2**

Name and address of the site : Rentschler Biopharma SE, Erwin-Rentschler-Strasse 21, Laupheim, Baden-Wuerttemberg, 88471, Germany

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.3 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.2 Batch Certification (list of product types) 1.3.2.2 Immunological products 1.3.2.5 Biotechnology products
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.3 Other: Active pharmaceutical ingredients, biotechnologically manufactured: recombinant proteins, monoclonal antibodies, cytokines, mRNA-based APIs(en)
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 (for Public users)

ad 1.4.1.3: Authorised manufacturing or importation covers batch certification. According to the facility Layouts, dated September 24, 2020.

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.1 Microbiological: sterility 2.1.2 Microbiological: non-sterility 2.1.3 Chemical/Physical 2.1.4 Biological

2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	2.2.3 Biological medicinal products 2.2.3.2 Immunological products 2.2.3.5 Biotechnology products

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

ad 2.2.3.2: Recombinant manufactured sera and vaccines ONLY. ad 2.2.3.5: Medicinal products, biotechnologically manufactured: recombinant proteins, monoclonal antibodies, cytokines.