MANUFACTURER'S AUTHORISATION [1, 2]

1. Authorisation Number	DE_BW_01_MIA_2020_0096
2. Name of authorisation holder	Roche Pharma AG
3. Address(es) of manufacturing site(s)	Roche Pharma AG (ORG-100001131 / LOC-100004781), Emil-Barell-Strasse 1, Grenzach-Wyhlen, Baden-Wuerttemberg, 79639, Germany
4. Legally registered address of authorisation holder	Emil-Barell-Str. 1, Grenzach-Wyhlen, Baden-Wuerttemberg, 79639, Germany
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. 13 of Directive 2001/20/EC
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	confidential
8. Signature	
9. Date	2021-01-20
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: Roche Pharma AG, Emil-Barell-Strasse 1, Grenzach-Wyhlen, Baden-Wuerttemberg, 79639, Germany

Additional Details:

Human 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
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.2 Batch Certification (list of product types) 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)

This authorisation is based on plans, dated October 19, 2020. Includes storage of medicinal products at the address Warmbacher Str. 80, D-79618 Rheinfelden.

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
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
	2.2.2 Non-sterile products
	2.2.3 Biological medicinal products 2.2.3.4 Gene therapy products 2.2.3.5 Biotechnology products
2.3	**Other importation activities**
	2.3.1 Site of physical importation

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

Ad 2.2.1 and 2.2.2: Authorised manufacturing is restricted to the batch certification of: - Liquids - Semi-solids - Solids Ad 2.3.1: relates to the storage areas at the address Warmbacher Str. 80, D-79618 Rheinfelden This authorisation is based on plans, dated October 19, 2020.

SCOPE OF AUTHORISATION **ANNEX 2**

Name and address of the site : Roche Pharma AG, Emil-Barell-Strasse 1, Grenzach-Wyhlen, Baden-Wuerttemberg, 79639, 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
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.2 Batch Certification (list of product types) 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)

This authorisation is based on plans, dated October 19, 2020. Includes storage of medicinal products at the address Warmbacher Str. 80, D-79618 Rheinfelden.

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
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
	2.2.2 Non-sterile products
	2.2.3 Biological medicinal products 2.2.3.4 Gene therapy products 2.2.3.5 Biotechnology products
2.3	**Other importation activities**
	2.3.1 Site of physical importation

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

Ad 2.2.1 and 2.2.2: Authorised manufacturing is restricted to the batch certification of: - Liquids - Semi-solids - Solids Ad 2.3.1: relates to the storage areas at the address Warmbacher Str. 80, D-79618 Rheinfelden. This authorisation is based on plans, dated October 19, 2020.