AGENZIA ITALIANA DEL FARMACO

Certificate No: IT/26/H/2021

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC

The competent authority of Italy confirms the following:
The manufacturer DEPO-PACK S.R.L.
Site address VIA MORANDI, 28 - 21047 SARONNO (VA)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aAMM - 35/2021 dated 02/18/2021 in accordance with Art. 40 of Directive 2001/83/EC/ transposed in the following national legislation: D. Lvo 219/2006 Art. 50.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 03/15/2018, it is considered that it complies with the Good Manufacturing Practice requirements referred to in The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection, after which time the issuing authority should be consulted.
The authenticity of this certificate may be verified with the issuing authority.

AIFA: Italian Medicines Agency
GMP Inspections and Manufacturing Authorizations of Medicinal Products Office
Via del Tritone, n° 181 - 00187 ROMA (ITALY)
Tel.+390659784410 Fax +390659784312
website: www.agenziafarmaco.it
SIS : 1370

RS
GMP

AGENZIA ITALIANA DEL FARMACO

Part 2

Name and address of the site:	DEPO-PACK S.R.L. - VIA MORANDI, 28 21047 SARONNO (VA)

Human Medicinal Products

Authorised Operations Manufacturing Operations (Part 1) Importation of medicinal products (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
1.5	**Packaging**
	1.5.2 Secondary packing

PART 2 - IMPORTATION OF MEDICAL PRODUCTS	
2.2	**Batch certification only (list of product types)**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared products 2.2.1.2 Terminally sterilised *2.2.2 Non-sterile products*
2.3	**Other importation activities**
	2.3.1 Site of physical importation *2.3.2 Importation of intermediate which undergoes further processing*

Any restrictions or clarifying remarks related to the scope of these Importing operations:
2.3.2 Importation of intermediate which undergoes further processing: secondary packaging.

AGENZIA ITALIANA DEL FARMACO

Name and address of the site:	DEPO-PACK S.R.L. - VIA MORANDI, 28 21047 SARONNO (VA)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)
Importation of medicinal products (Part 2)

PART 1 - MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS

1.1	**Sterile investigational medical products**	
	1.1.3	*Batch certification*
1.2	**Non-sterile investigational medical products**	
	1.2.2	*Batch certification*
1.3	**Biological investigational medicinal products**	
	1.3.2	*Batch certification*
		1.3.2.5 Biotechnology products
1.5	**Packaging**	
	1.5.2	*Secondary packing*

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations:

1.3.2.5 Biotechnology products: Monoclonal Antibodies.

PART 2 - IMPORTATION OF INVESTIGATIONAL MEDICAL PRODUCTS

2.2	**Batch certification of imported of investigational medical products**	
	2.2.1	*Sterile products*
		2.2.1.1 Aseptically prepared products
		2.2.1.2 Terminally sterilised
	2.2.2	*Non-sterile products*
	2.2.3	*Biological medicinal products*
		2.2.3.5 Biotechnology products

2.3	Other importation activities	
	2.3.1	*Site of physical importation*
	2.3.2	*Importation of intermediate which undergoes further processing*

Any restrictions or clarifying remarks related to the scope of these Importing operations:

2.2.3.5 Biotechnology products: Monoclonal antibodies;

2.3.2 Importation of intermediate which undergoes further processing: secondary packaging.

Rome, 02/22/2021

Name and signature of the authorised person of the Competent Authority of Republic of Italy

AGENZIA ITALIANA DEL FARMACO

E' copia conforme all'originale
composta di n. ....4..... fogli
Roma il 06/05/2021

Renato Massimi
GMP Inspections and Manufacturing
Authorizations of Medicinal Products Office

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