

Certificate No: IT/238/H/2024

## **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 EUROFINS BIOLAB SRL

Site address VIA B. BUOZZI, 2 - 20055 VIMODRONE (MI)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 171/2024 dated 11/28/2024 in accordance with Art. 40 of Directive 2001/83/EC/ transposed in the following national legislation: D. Lvo 219/2006 Art. 50, Art. 13 of Directive 2001/20/EC transposed in the following national legislation: D. Lvo 211/2003 Art. 13 and Art. 63 of the Regulation (EU) 536/2014.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 09/13/2024, 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.

**Part 2**

Name and address of the site: EUROFINS BIOLAB SRL - VIA B. BUOZZI, 2 , 20055  
VIMODRONE(MI)

Human Medicinal Products

**Authorised Operations**

Manufacturing Operations (Part 1)

Importation of medicinal products (Part 2)

**PART 1 - MANUFACTURING OPERATIONS**

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:**

Also quality control testing for active substances batch certification;

1.6.4 Biological: In vivo test, In vitro test and Endotoxins test (LAL test);

**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

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

Also quality control testing for active substances batch certification;

2.1.4 Biological: In vivo test, In vitro test, Endotoxins test (LAL test);

Name and address of the site: EUROFINS BIOLAB SRL - VIA B. BUOZZI, 2 , 20055  
VIMODRONE(MI)

Human Medicinal Products

## Authorised Operations

Manufacturing Operations (Part 1)

### PART 1 - MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS

1.6	Quality control testing
	1.6.1 <i>Microbiological: sterility</i>
	1.6.2 <i>Microbiological: non-sterility</i>
	1.6.3 <i>Chemical/Physical</i>
	1.6.4 <i>Biological</i>

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

Also quality control testing for active substances batch certification;

1.6.4 Biological: In vivo test, in vitro test and Endotoxin test (LAL test);

Rome, 11/28/2024

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

Angela Del Vecchio  
GMP Inspections and Manufacturing  
Authorizations of Medicinal Products Office

STAMP DUTY PAID ACCORDING TO THE CURRENT ITALIAN LAW