Certificate No: IT/166/H/2026

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 STRADA DELLE FRIGGE 7 (loc. MONTERIGGIONI) - 53035 MONTERIGGIONI (SI)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 128/2026 dated 08/21/2026 in accordance with Art. 40 of Directive 2001/83/EC/ transposed in the following national legislation: D. Lvo 219/2006 Art. 50 and Art. 61 of the Regulation (EU) 536/2014.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 07/15/2026, 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.+390659784357 Fax +390659784312
website: www.agenziafarmaco.it
SIS : 963

PC
GMP

Part 2

Name and address of the site:	EUROFINS BIOLAB SRL - STRADA DELLE FRIGGE 7 (loc. MONTERIGGIONI) , 53035 MONTERIGGIONI(SI)

Human Medicinal Products

Authorised Operations

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

PART 1 - MANUFACTURING OPERATIONS

1.6	**Quality control testing**	
	1.6.2	*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 of active pharmaceutical ingredients and intermediates;
1.6.4 Biological: endotoxin testing;

PART 2 - IMPORTATION OF MEDICINAL PRODUCTS

2.1	**Quality control testing of imported medicinal products**	
	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:

Including quality control testing of active pharmaceutical ingredients;
2.1.4 Biological: Endotoxin testing;

Name and address of the site: EUROFINS BIOLAB SRL - STRADA DELLE FRIGGE 7 (loc. MONTERIGGIONI) , 53035 MONTERIGGIONI(SI)

Human Medicinal Products

Authorised Operations

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

PART 1 - MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS

1.6	**Quality control testing**	
	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:

Including quality control testing of active pharmaceutical ingredients;
1.6.4 Biological: endotoxin testing;

PART 2 - IMPORTATION OF INVESTIGATIONAL MEDICINALPRODUCTS

2.1	**Quality control testing of imported investigational medicinal products**	
	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 of active pharmaceutical ingredients;
2.1.4 Biological: endotoxin testing;

Rome, 08/21/2026

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

Fabrizio Sacco
GMP Inspections and Manufacturing
Authorizations of Medicinal Products Office

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SACCO
25.08.2026
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GMT+02:00

STAMP DUTY PAID ACCORDING TO THE CURRENT ITALIAN LAW

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