

Certificate No: IT/33/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 VIA RENO, 2 - 53036 POGGIBONSI (SI)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 26/2026 dated 02/23/2026 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 12/18/2025, 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 RENO, 2 , 53036 POGGIBONSI(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 <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 tests of active substances and intermediates;

1.6.4 Biological: bacterial endotoxins test;

PART 2 - IMPORTATION OF MEDICINAL PRODUCTS

2.1	Quality control testing of imported medicinal products
	2.1.2 <i>Microbiological: non-sterility</i>
	2.1.3 <i>Chemical/Physical</i>
	2.1.4 <i>Biological</i>

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

Also quality control tests of active substances;

2.1.4 Biological: bacterial endotoxins test;

Name and address of the site: EUROFINS BIOLAB SRL - VIA RENO, 2 , 53036 POGGIBONSI(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 <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 tests of active substances;

1.6.4 Biological: bacterial endotoxins test;

PART 2 - IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS

2.1	Quality control testing of imported investigational medicinal products
	2.1.2 <i>Microbiological: non-sterility</i>
	2.1.3 <i>Chemical/Physical</i>
	2.1.4 <i>Biological</i>

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

Also quality control tests of active substances;

2.1.4 Biological: bacterial endotoxins test;

Rome, 02/23/2026

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

Republic of Italy



FABRIZIO SACCO
24.02.2026
08:07:35
GMT+01:00

Fabrizio Sacco

GMP Inspections and Manufacturing
Authorizations of Medicinal Products Office

STAMP DUTY PAID ACCORDING TO THE CURRENT ITALIAN LAW