

Certificate No: IT/80/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 MM OPERATIONS SRL

Site address VIA MILANO,2 - 24040 CALVENZANO (BG)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 61/2026 dated 05/08/2026 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 12/12/2025, 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: MM OPERATIONS SRL - VIA MILANO,2 , 24040 CALVENZANO(BG)

Human Medicinal Products

<b>Authorised Operations</b>	
Manufacturing Operations (Part 1)	
Importation of medicinal products (Part 2)	
<b>PART 1 - MANUFACTURING OPERATIONS</b>	
<b>1.5</b>	<b>Packaging</b>
	1.5.2 <i>Secondary packing</i>

<b>PART 2 - IMPORTATION OF MEDICINAL PRODUCTS</b>	
<b>2.3</b>	<b>Other importation activities</b>
	2.3.1 <i>Site of physical importation</i>
	2.3.4 <i>Other</i>

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

2.3.4 Other: secondary packaging activity;

Name and address of the site: MM OPERATIONS SRL - VIA MILANO,2 , 24040 CALVENZANO(BG)

Human Medicinal Products

<b>Authorised Operations</b>	
Manufacturing Operations (Part 1)	
Importation of medicinal products (Part 2)	
<b>PART 1 - MANUFACTURING OPERATIONS OF</b>	

## INVESTIGATIONAL MEDICINAL PRODUCTS

<b>1.5</b>	<b>Packaging</b>
	1.5.2 <i>Secondary packing</i>

## PART 2 - IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS

<b>2.3</b>	<b>Other importation activities</b>
	2.3.1 <i>Site of physical importation</i>
	2.3.4 <i>Other</i>

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

2.3.4 Other: secondary packaging;

Rome, 05/08/2026

**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

STAMP DUTY PAID ACCORDING TO THE CURRENT ITALIAN LAW

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