Certificate No: IT/46/H/2023

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 BIOFARMA S.R.L.
Site address VIA CASTELLIERE,2 - 33036 MERETO DI TOMBA (UD)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 42/2023 dated 03/16/2023 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 02/03/2023, 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 : 4707

PC
GMP

Part 2

Name and address of the site:	BIOFARMA S.R.L. - VIA CASTELLIERE,2 , 33036 MERETO DI TOMBA(UD)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS

1.2	**Non-sterile products**		
	1.2.1	*Non-sterile products*	
		1.2.1.1	Capsules, hard shell
		1.2.1.8	Other solid dosage forms
1.3	**Biological medicinal products**		
	1.3.1	*Biological medicinal products*	
		1.3.1.8	Other organic medicinal products
1.5	**Packaging**		
	1.5.1	*Primary packing*	
		1.5.1.1	Capsules, hard shell
		1.5.1.6	Liquids for internal use
		1.5.1.8	Other solid dosage forms
	1.5.2	*Secondary packing*	
1.6	**Quality control testing**		
	1.6.2	*Microbiological: non-sterility*	
	1.6.3	*Chemical/Physical*	

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

1.2.1.1 Capsules, hard shell: only live biotherapeutic products;

1.2.1.8 Other solid dosage forms: powder: only live biotherapeutic products;

1.3.1.8 Other organic medicinal products: Live biotherapeutic products;

1.5.1.1 Capsules, hard shell: only live biotherapeutic products;
1.5.1.6 Liquids for internal use: only live biotherapeutic products;
1.5.1.8 Other solid dosage forms: powder: only live biotherapeutic products;

Rome, 03/16/2023

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

DEL VECCHIO
ANGELA
AIFA - AGENZIA
ITALIANA DEL
FARMACO
Dirigente
16.03.2023 13:36:31
GMT+00:00

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

STAMP DUTY PAID ACCORDING TO THE CURRENT ITALIAN LAW

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