



Agenzia Italiana del Farmaco

Certificate No: IT/79-1/H/2018

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 S.C.F. S.R.L.

Site address VIA F.BARBAROSSA,7 - 26824 CAVENAGO D'ADDA (LO)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 20/2018 dated 02/06/2018 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 12/14/2017, 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.+390659784410 Fax +390659784312
website: www.agenziafarmaco.it
SIS : 3412

IV
GMP



Agenzia Italiana del Farmaco

Part 2

Name and address of the site: S.C.F. S.R.L. - VIA F.BARBAROSSA,7 , 26824 CAVENAGO D'ADDA(LO)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS

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

Name and address of the site: MAGAZZINO - VIA F. BARBAROSSA, 6 - 26824 - CAVENAGO D'ADDA (LO)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

Importation of medicinal products (Part 2)

PART 1 - MANUFACTURING OPERATIONS

1.4	Other products or manufacturing activity
	1.4.3 <i>Others: storage</i>

PART 2 - IMPORTATION OF MEDICAL PRODUCTS

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

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Name and address of the site: **MAGAZZINO-DEPOSITO DI SOLO MATERIALE STAMPATO - VIA F. BARBAROSSA, 9 - 26824 - CAVENAGO D'ADDA (LO)**

Human Medicinal Products

Authorised Operations	
Manufacturing Operations (Part 1)	
PART 1 - MANUFACTURING OPERATIONS	
1.4	Other products or manufacturing activity
	1.4.3 Others: storage

Rome, 03/08/2018



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

Dott. Renato Massimi
GMP Inspections and Manufacturing Authorizations of Medicinal Products Office



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