



Agenzia Italiana del Farmaco

Certificate No: IT/77-1/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 G. COMPAGNONI OSSIGENO S.R.L.

Site address VIA TORINO, 26 - 80040 VOLLA (NA)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aG - 3/2018 dated 01/31/2018 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 11/24/2017, 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 : 1162



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Part 2

Name and address of the site:

G. COMPAGNONI OSSIGENO S.R.L. - VIA TORINO, 26 , 80040 VOLLA(NA)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS

1.2	Non-sterile products
	1.2.2 <i>Batch certification</i>
1.5	Packaging
	1.5.1 <i>Primary packing</i>
	1.5.1.7 <i>Medicinal gases</i>
1.6	Quality control testing
	1.6.3 <i>Chemical/Physical</i>

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

1.5.1.7 Medicinal gases: Liquid oxygen in dewards; gas oxygen in cylinders;;

1.6.3 Chemical/Physical: medical gases ;





Agenzia Italiana del Farmaco

Rome, 03/06/2018



**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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