



Viale Stucchi, 62/26

20900 Monza

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July 10<sup>th</sup>, 2025

To Whom It May Concern,

The following information is being provided in support of the following license holder:

**Redox Srl**  
**Via Gian Battista Stucchi 62/26 and 62/1, Monza, 20900, Italy (ITA)**

**GMP Certificate**

The FDA does not issue formal GMP certificates to sites, as is the practice with other countries. However, I certify that the facility, systems, and procedures for products manufactured at this facility undergo routine inspections. A listing of recent inspections at **Via Gian Battista Stucchi 62/26 and 62/1, Monza, 20900, Italy (ITA)** location (Figure 1) can be found at:  
<https://datadashboard.fda.gov/ora/cd/inspections.htm>.

**Manufacturing License**

From 01-Jun-2009 onward, the US FDA no longer issues a hardcopy of the drug establishment registrations but requires companies to submit information electronically. The current registration status (Figure 2) can be found on the FDA website:  
<http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm>.

The full FDA Guidance can be found at:

<http://www.fda.gov/downloads/drugs/guidanceComplianceRegulatoryInformation/guidances/ucm072339.pdf>.

This is to certify that the attached document is a true and accurate copy of the current search results from the above-mentioned websites as proof of the current registration status of **Redox Srl** located at **Via Gian Battista Stucchi 62/26 and 62/1, Monza, 20900, Italy (ITA)** with the US FDA.

Regards,

Name Patrizia Colombo

Title QA/ 2<sup>nd</sup> QP

Date

Figure 1- GMP Certificate

Inspections Details [Help](#)

Record Count: 5

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Select Inspection ID(s) to view corresponding Inspections Citations.

FEI Number	Legal Name	City	State	Zip	Country/Area	Fiscal Year	Inspection ID	Posted Citations	Inspection End Date	Classification	Project Area	Product Type	Additional Details
<a href="#">3006720740</a>	Redox S.r.l.	Monza	-	-	Italy	2023	1269520	No	03/08/2023	Voluntary Action Indicated (VAI)	Drug Quality Assurance	Drugs	Mutual Recognition
<a href="#">3006720740</a>	Redox S.r.l.	Monza	-	-	Italy	2019	1119645	No	05/24/2019	Voluntary Action Indicated (VAI)	Drug Quality Assurance	Drugs	Mutual Recognition
<a href="#">3006720740</a>	Redox S.r.l.	Monza	-	-	Italy	2015	917270	No	02/20/2015	Voluntary Action Indicated (VAI)	Drug Quality Assurance	Drugs	-
<a href="#">3006720740</a>	Redox S.r.l.	Monza	-	-	Italy	2015	917270	No	02/20/2015	No Action Indicated (NAI)	Unapproved and Misbranded Drugs	Drugs	-
<a href="#">3006720740</a>	Redox S.r.l.	Monza	-	-	Italy	2011	747478	No	09/28/2011	Voluntary Action Indicated (VAI)	Drug Quality Assurance	Drugs	-

Figure 2- Manufacturing License

 U.S. FOOD & DRUG ADMINISTRATION

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Drug Establishments Current Registration Site

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Showing 1 to 1 of 1 entries

Show 50 entries

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
Redox Srl	3006720740	439196391	ANALYSIS	Via Gian Battista Stucchi 62/06, Monza, 20900, Italy (ITA)	12/31/2025

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**Figure 3 – SPOR EMA organization registration**

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spor.ema.europa.eu/oms/wi/#searchedOrganisations/viewLocation/LOC-100021829

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## Organisation Details

Organisation ID:	ORG-100012125
Organisation Name:	Redox S.r.l.
Status:	ACTIVE
Organisation Type:	Industry Pharmaceutical company

## Location Details

Location ID:	LOC-100021829
Address:	<div>EN ▼</div> <div>Viale Gian Battista Stucchi 62/26</div> <div>Moriza</div> <div>MB</div> <div>20900</div> <div>Italy</div>
GPS Location:	45.582619, 9.31044
Location Email:	quality@labredox.com
Location Phone:	39 392847434
DUNS ID:	439198391
EudraGMDP Number:	8502
Last Modified Date:	2024-10-11T10:26:42
Status:	ACTIVE

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