

	G.M.P. (EU) <i>Aut. Prod.</i> <i>Prov. Ric. n. CE IT AIP 19038</i>	<i>Valeo Farma S.p.A.</i> <i>C/da Canne Masche s.n.c.</i> <i>90018 Z. I.</i> <i>Termini Imerese, Italy</i> <i>P. Iva (VAT) 06288220822</i>
Prepared by: Dr. Francesco Gullo	Verified by: Dr. Giuseppe Farina	Approved by: Dr. Vincenzo Licalsi
Code: Release_CoA	Rev. 8	Emission date: 28/04/2025

CERTIFICATE OF ANALYSIS OF FINISHED PRODUCT

Certificate Number	Product Name	Owner of Product
482/25	VITAMINA B12	NUTRAMIS SRL

Batch Number	Production Date	Expiry Date
NB250616	16/06/2025	07/2028

Product Category	FOOD SUPPLEMENT FOR HUMAN USE
Storage Conditions	15-25°C, 35-60% RH

APPEARANCE

Pharmaceutical form	TABLET
Primary Packaging	PILL JAR
Secondary Packaging	N.A.
Accessories	N.A.

Declaration of Compliance

We hereby declare that this product is a food supplement as defined by Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002. This product complies with the specifications of the Codex Alimentarius, with European food legislation with Regulations (EU) 178/2002, 852/2004 and 382/2021, and with HACCP, GMP and GHP criteria. The testing laboratories that performed the checks are aligned with the UNI CEI EN ISO 17025:2018 standard.

MICROBIOLOGICAL TESTS

Test	U.M.	Method	Result	Limits*
Total Aerobic Microorganisms	c.f.u./g	ISO 4833-1	< 10	≤20.000
Total Moulds-Yeasts	c.f.u./g	ISO 21527-2	< 10	≤200
Enterobacteriaceae	c.f.u./g	ISO 21528-2	< 10	≤200
E. coli	c.f.u./g	ISO 16649-3	Absent	Absent
Salmonella	c.f.u./g	EU.PH	Absent	Absent
Staphylococcus aureus	c.f.u./g	EU.PH	Absent	Absent

*In accordance to acceptance criteria for microbiological quality of non-sterile dosage forms (Eu.Ph)

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ADDITIONAL TESTS				
(tests performed in an external laboratory)				
Test	U.M.	Method	Result	Limits*
Gluten	mg/Kg	[MI] PPA-287 rev3 2022	< 5,0	< 20
Lactose	mg/Kg	[MI] PPA-297 rev2 2022	< 5	N.A
* Gluten limit in accordance to REG.(EC) N. 828/2014				

OTHER INFORMATION PROVIDED ON RAW MATERIALS AND PACKAGING MATERIALS
- Compliant to Reg. UE 2023/915 < 10 ppm Heavy Metals (Pb < 3 ppm; Cd < 1 ppm; Hg < 0,1 ppm). < 5 ppb aflatoxin B1 < 10 ppb total aflatoxin (sum of B1, B2, G1, G2). < 400 ppb Pyrrolizidine alkaloids < 10 ppm benzoapyrene, < 50 ppm IPA4 - And other contaminants. - Compliant to Reg. UE 1169/2011 about nanomaterials. - Compliant to Reg. CE 396/2005 and 839/2008 about residual pesticides. - Compliant to Dir. CE 1999/2/CE and 1999/3 about product not irradiated. - Compliant to Dir. 2009/32/CE about residual solvents. - Compliant to Reg. CE 1935/2004 about packaging materials. - Compliant to Reg. CE 2073/2005 about microbiological criteria Product does not contain, and it is not manufactured from OMG components.

Rating: Suitable
Date of release: 27/06/2025

Authorized by: Dr. Vincenzo Licalsi

Valeo Farma S.p.A.
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