

**Allergen Servilab S.L.:**

**REGULATORY MANUFACTURING STATEMENT**

The products we collect, produce and supply are handled under the following rules and guidelines:

- **Quality Management System ISO 9001:2015.**
- **European Pharmacopeia monographs:**
  - a) Pollen 01/2017:2627
  - b) Mould 01/2017:2626
  - c) Mite 01/2017:2625
  - d) Animal Epithelia and outgrowths 01/2017:2621
- **Guideline on Good Agricultural and Collection Practice (GACP) for starting materials of herbal origin. EMEA/HMPC/246816/2005. (For pollen)**

Under current European legislation, we are not able to receive a GMP Certificate for the Allergen Source Materials produced on site as they are not considered Active Pharmaceutical Ingredients (API) by the Medical Authority.

**Allergen Servilab S.L.**

La Horcajada, Avila. España

June, 2021.



www.imq.it



IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATE N. 0366.2021
CERTIFICADO N.

WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY
CERTIFICA QUE EL SISTEMA DE GESTIÓN DE CALIDAD DE

ALLERGEN SERVILAB, S.L.

C/ LA ALDEHUELA 97 - 05695 LA HORCAJADA (ÁVILA) SPAIN

OPERATIVE UNITS / INSTALACIÓN DE



Allergen Servilab

C/ LA ALDEHUELA 97 - 05695 LA HORCAJADA (ÁVILA) SPAIN

IS IN COMPLIANCE WITH THE STANDARD / REÚNE LOS REQUISITOS DE LA NORMA

ISO 9001:2015

FOR THE FOLLOWING ACTIVITIES / PARA LAS SIGUIENTES ACTIVIDADES

Recolección de todo tipo de materiales biológicos. Producción de materias primas biológicas (polen, partes vegetales, ácaros, hongos, epitelios) para productos alergénicos de uso en la industria farmacéutica y biosanitaria en general. Comercialización de materias primas biológicas
Collection of any kind of biological materials. Production of biological raw materials (pollen, vegetable parts, mites, moulds, epitheliums) as allergenic products for use in pharmaceutical and biosanitary industry. Commercialization of biological raw materials

Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization
Cualquier aclaración adicional relativa a la aplicación de la norma ISO 9001:2015, puede obtenerse consultando a la organización

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS
EL PRESENTE CERTIFICADO ESTÁ SUJETO AL RESPETO DEL REGLAMENTO PARA LA CERTIFICACIÓN DE LOS SISTEMAS DE GESTIÓN

Table with 3 columns: DATES, FIRST CERTIFICATION, CURRENT ISSUE, EXPIRY. Values include 2021-03-24, 2021-03-24, 2024-03-23.

Handwritten signature of Flávio Ornago

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flávio Ornago



www.cisq.com



SGQ N° 005 A

IAF: 12, 13, 35, 29

Organismo di Certificazione Federato CISQ
www.imq.it

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale. CISQ is the Italian Federation of management system Certification Bodies.

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years
La validez del certificado está sujeta a auditorías anuales y a la recertificación completa del Sistema de Gestión con una periodicidad trienal



THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

*CISQ/IMQ has issued an IQNet recognized certificate that the organization:*

**ALLERGEN SERVLAB, S.L.**

C/ LA ALDEHUELA 97 - 05695 LA HORCAJADA (ÁVILA) SPAIN

*has implemented and maintains a*

*Quality Management System*

*for the following scope:*

**Collection of any kind of biological materials. Production of biological raw materials (pollen, vegetable parts, mites, moulds, epitheliums) as allergenic products for use in pharmaceutical and biosanitary industry. Commercialization of biological raw materials**

*Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization*

*which fulfills the requirements of the following standard:*

**ISO 9001:2015**

*Issued on: 2021 - 03 - 24*

*Expires on: 2024 - 03 - 23*

*This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document*

**Registration Number: IT - 131606**



*Alex Stoichitoiu  
President of IQNET*



*Ing. Mario Romersi  
President of CISQ*

**IQNet Partners\*:**

- AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy
- CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA
- FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifointi Oy Finland INTECO Costa Rica
- IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
- NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
- SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

\* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under [www.iqnet-certification.com](http://www.iqnet-certification.com)