

MITELOS QUALITY POLICY

Mitelos Bioscience S.L. (Mitelos) is a private, dynamic and independent pharmaceutical company that designs, develops, controls manufacturing, distributes to different countries through other pharmaceutical companies and the health sector and carries out post-market surveillance of medical devices and food supplements within the selected areas of interest.

Mitelos has implemented and maintains a Quality Management System based on the requirements of EN ISO 13485:2016 whose certification has the following scope:

"Design and control of the manufacture of non-sterile liquids for otic applications".

Mitelos considers Quality as an essential factor, both for its products and its services. It is for this reason that a MITELOS QUALITY POLICY has been created, applicable to the purpose of the organization, to be complied with by the Company's employees and companies working on its behalf.

The general guidelines that, in relation to Quality, guide Mitelos are:

- Ensure that the products supplied to our customers are safe, reliable and comply with applicable specifications, standards and regulatory requirements.
- Maintain close cooperation with our distributors (customers) giving continuous advice on our products.
- Obtain maximum customer satisfaction through the service offered, as well as through the quality of the products supplied.
- Maintain permanent contact with customers and suppliers, collaborating together in the design and improvement of our products.
- Promote good collaboration and mutual benefit with subcontractors and our customers.
- Establish actions aimed at prevention, not just detection and correction.
- Promote efficient internal and external communication within the scope of the Quality Management System.
- That the whole organization is aware of the Policy and applies it on a daily basis, with a commitment by all to comply with the requirements and maintain the effectiveness of the Quality Management System. The Management is committed to maintain the effectiveness of the Quality Management System and to provide the necessary resources and training to promote the maintenance of the effectiveness of the Quality Management System, increasing and motivating the competences of Mitelos staff.
- Management is committed to comply with regulatory requirements and with the requirements of EN ISO 13485:2016.
- Establish quality objectives consistent and measurable with the Quality Policy.

For this, the Mitelos Management undertakes to review this Policy once a year for its continuous adaptation.



www.imq.it

CISQ is a member of



THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com

*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. 0831.2020

CERTIFICADO N.

WE HEREBY CERTIFY THAT THE MANAGEMENT SYSTEM OPERATED BY
CERTIFICAMOS QUE EL SISTEMA DE GESTIÓN DE

MITELOS BIOSCIENCE, S.L.

RONDA CAN FATJÓ 7B - 08290 CERDANYOLA DEL VALLÈS (BARCELONA) SPAIN

OPERATIVE UNITS / *INSTALACIÓN DE*



RONDA CAN FATJÓ 5-D - 08290 CERDANYOLA DEL VALLÈS (BARCELONA) SPAIN

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

ISO 13485:2016

FOR THE FOLLOWING ACTIVITIES / *PARA LAS SIGUIENTES ACTIVIDADES*

Diseño y control de la fabricación de soluciones no estériles para aplicación óptica
Design & control of manufacture of non sterile liquids for otic applications

Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization
Cualquier aclaración adicional relativa a la aplicación de la norma ISO 13485:2016, 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*

DATES:	<i>FIRST CERTIFICATION</i>	<i>CURRENT ISSUE</i>	<i>EXPIRY</i>
	<i>PRIMERA CERTIFICACIÓN</i>	<i>EMISION ACTUAL</i>	<i>VÁLIDO HASTA</i>
	2020-06-29	2020-06-29	2023-06-28

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



SGQ N° 005 A

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 auditorias anuales y a la recertificación completa del Sistema de Gestión con una periodicidad trienal



Organismo di Certificazione Federato CISQ
www.imq.it



www.cisq.com

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