



MANUAL DE GESTION INTEGRADA

REVISION

15

FECHA

23/03/2020

ANNEX 2. COMPANY'S DECLARATION OF INTEGRATED POLICY

AJL OPHTHALMIC, S.A., is a company committed to quality and service to health, that starts its activity in April 1998 in the design, production and distribution of medical devices in the field of ophthalmology.

From its beginnings, AJL has been a company which has been heavily committed to R&D activities. For AJL, research into new products, markets or improving those which already exist, in close collaboration with the most prestigious ophthalmologists from both national and international fields, is one of the underpinnings which support the entire business structure and that's where we focus our efforts.

The capacity to adapt to new times is a constant for AJL and this has encouraged diversification and incursion into new markets, for example that of veterinary ophthalmology, in which AJL currently already designs, manufactures and also distributes its products.

AJL has committed itself to incursion into the American market thanks to the acquisition of the American company Addition Technology, through which it has positioned itself as world leader in Keratoconus and has managed to exponentially promote its products at an international level.

Our mission is to offer our customers quality products and services, providing solutions to existing and future demands. For that reason, we comply with the applicable regulation requirements and we work in the constant improvement of all our processes in order to achieve being competitive with our sector's multinationals.

The fundamental values promoted in the company are **the quality work, team-work and customer service**.

AJL S.A. is aware of the current and growing environmental problematic, and as a supporter of the sustainable development, is committed to prevention, protection and conservation of the environment in all its activities. For this purpose a Head of Quality and Environment has been designate in order to achieve the proposed goals and gaining a commitment to pollution prevention.

This is intended to minimize the environmental impact of our activity by controlling our significant environmental aspects as the generation of hazardous waste and energy consumption. For this, it will be established an Environmental Plan which sets out the objectives and goals of AJL Ophthalmic, S.A. These objectives and goals were based on the decrease of waste generated in all processes and its proper treatment, the decrease of energy consumption and raw materials.

The **People** of the Organization are the fundamental engine of its work and results. For that reason, our **main objective** is to achieve not only all the satisfaction of its expectative and needs, by means of its **motivation and integration** into the Organization, but also to guarantee the safety and health for each and every one of its employees.

The **Board of Directors** assumes, as its own responsibility, to carry out the leadership of the **quality's Management, Environmental Management and the occupational safety** acting as the driving force, guide and example of performing an obligation that involves all people working in it.

AJL's **Board of Directors** assume the responsibility of creating, implementing and maintaining, at all levels of the Organization, an **Integrated Management System** according to this integrated policy and in compliance with the regulations and legislation applicable to our activity and the products we manufacture.



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We are currently complying with the requirements of the **European directive 93/42 / EEC** transposed into national legislation by **Royal Decree 1591/2009** and **UNE-EN ISO 13485**, law on the prevention of **occupational Risks 31/1995 (mod. 54 / 2003)**, the American regulation on medical devices (**FDA Quality System Regulation 21 CFR 820**), the applicable legislation according to **RDC 16/2013, Brazil and ISO 14001**.

AJL, S.A. has provided the necessary financial, material and human resources to adapt our Quality system to the requirements of the **new European regulation 2017/745 MDR** that replaces the Directive on medical devices (93/42 / EEC). Which will take effect on May 26, 2020.

For that aim, it does not hesitate to make use of the collaboration of each and every one of the people belonging to AJL and it shows publicly the relevance and commitment to:

- ✚ Meet with the legal and regulation requirements of its customers as well as legal and any other requirement related to its environmental issues that the organization subscribes.
- ✚ Establish, review and update the Organization's aim.
- ✚ Provide the necessary resources for the application of the Integrated Management System.
- ✚ Work in the improvement and maintenance of the Organization's efficacy and its results.
- ✚ Communicate and make the Integrated Policy understood.
- ✚ Review periodically the Integrated Policy in order to guarantee its continuous adaptation.

All the procedures of the Integrated Management System have been developed with an **approach based on the management of risks present throughout the life cycle** of the product, including outsourced processes. For this, a DAFO study has been carried out to achieve this, achieving an efficient and compliant operation.

With this policy, AJL even tries to "bother" international multinationals of the sector due to our products' and services' quality and to be among the most important three companies in the ophthalmological market in Spain. Furthermore, aims to be among the most efficient companies in environment care within our sector business in our community. This aim will be achieved thanks to the work of a young team of quick response and total innovation.

P.J.SALAZAR
C.E.O. & PRESIDENT



The future of vision

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