



## POLICY AND OBJECTIVES FOR QUALITY AND ENVIRONMENT

SPINREACT, S.A.U. is a business dedicated to the manufacture, design and development and distribution of clinical in vitro diagnostic products, and to the manufacture, distribution, installation and service of instruments for clinical in vitro diagnosis.

The general management of SPINREACT, S.A.U. believes quality control and environmental protection are essential for the success of the company, and that all departments and personnel in the organisation are responsible for the tasks they perform.

The Integrated Quality and Environmental Management System, together with a process-based approach and compliance with environmental regulations and requirements, is intended to streamline resource allocation, control and prevent environmental impacts and risks, as well as increase our service efficiency. The aim is to achieve customer satisfaction while continually improving the environmental aspects and quality of our processes and products.

The SPINREACT, S.A.U. Quality System for reagents and Environmental protection has four overall objectives:

- Ensure that products meet specifications and comply with legal and regulatory requirements while also meeting the needs of the customer.
- Establish a system to implement the appropriate provisions for preventing and correcting non-conformities to guarantee product quality and environmental protection at all stages of product development.
- Continually improve our processes and products to consolidate and expand our market.
- We realise how important is to protect the environment and prevent pollution, not only at our production site but also wherever our products are found. We are committed to reducing CO2 emissions by improving facilities and processes and to reducing the waste generated by our products by optimising their packaging. The continuous identification and review of the environmental aspects during all lifecycle of our business and products allow us to implement the strategies required to ensure continuous improvement of our EMS.

Specific objectives are set annually, and the necessary monitoring is carried out to determine the degree of compliance.

Our policy and overall objectives are periodically reviewed and updated when necessary. They are also communicated and understood at all levels of the organisation because cooperation from the entire workforce is essential for meeting our goals. Annexe I (VMV version) will also be available on our website for all relevant stakeholders.

- As directed by the general management, the Quality Department of SPINREACT, S.A.U. will be responsible for determining the processes necessary for developing the Quality Management System (QMS), as well as for raising awareness of the importance of complying with customer requirements at all levels of the organisation.
- The general management of SPINREACT, S.A.U. will be responsible for establishing and maintaining the necessary processes for the Environmental Management System (EMS); as well as for raising awareness of the importance of complying with legal, regulatory and other requirements at all levels of the organisation.

GENERAL MANAGER

REV25 DATE: 05-2023





## MANAGEMENT STATEMENT

The general management assumes overall responsibility for all aspects of Quality and Environmental Management, both internal and external, with regard to all the activities carried out by SPINREACT, S.A.U. It delegates responsibility for environmental matters to the Environment Department, and responsibility for quality to the Quality Department, which shall undertake to implement and monitor measures to guarantee the quality of our services and products. However, all employees of SPINREACT, S.A.U., are directly responsible for ensuring the quality of their day-to-day work.

To comply with this responsibility, the Quality Department establishes procedures, standards and systems, and has the necessary resources to safeguard said responsibility. It will also notify the management of SPINREACT, S.A.U. of any incident or abnormality that may affect the quality of its products, processes, or environmental protection, potentially impacting the reputation of the company.

The Quality and Environment Manual provides an appropriate description of the Integrated Quality and Environmental Management System of SPINREACT, S.A.U., in accordance with the international EN-ISO 9001, UNE-EN ISO 14001 and ISO 13485 standards.

The practical application of these regulatory provisions ensures that all organisational and commercial activities that affect the quality of our products and environmental protection are planned, controlled and monitored.

The effectiveness of any activities related to quality and the environment, as well as the organisation and methods implemented by the Quality and Environmental Management System, are reviewed and verified by the management, to ensure they evolve in line with customer expectations.

The general management of SPINREACT, S.A.U. undertakes to ensure that all departments of the organisational structure contribute, as appropriate, to the fulfilment of this Quality and Environmental Policy, declaring it to be mandatory throughout the company.

GENERAL MANAGER

A handwritten signature in blue ink, appearing to be "A. G. P." followed by a wavy line.

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