

BIOLATEX considers that Quality has strategic importance. We believe that Quality affects the entire organization at all levels. It is not only critical to the success of the company, but also drives our competitiveness in international markets.

In order to comply with all applicable requirements, BIOLATEX has developed and implemented a Quality Management System designed in accordance with ISO 9001:2015, ISO 13485:2016 and Regulation (EU) 2017/746 on “medical devices for in vitro diagnostics”.

BIOLATEX is committed to:

- ✓ Ensure that products meet specifications and legal and regulatory requirements, while meeting customer needs and expectations
- ✓ Determine through risk-based approaches, the processes necessary to develop the Quality Management System (QMS), as well as to raise awareness of the importance of meeting customer requirements at all levels of the organization
- ✓ Provide customers with design and development services that meet or exceed agreed requirements, adding value to the quality of our products
- ✓ Establish a system to implement adequate provisions to prevent and correct nonconformities to ensure product quality at all stages of product development
- ✓ Continuously improve our processes and products to consolidate and expand our market
- ✓ Achieve customer satisfaction while continuously improving the quality of our products
- ✓ Ensure that the overall policy and objectives are regularly reviewed and updated as necessary
- ✓ Maintain a high level of satisfaction and adequacy of its staff, ensuring adequate training and guaranteeing safety and health at work
- ✓ Implement the strategies required to ensure environmental protection at all stages of product development

The general management of BIOLATEX undertakes that all the departments of the organizational structure contribute, as appropriate, to compliance with this Quality, declaring it mandatory throughout the company.

Asier Milla

General Manager

Date: February 20, 2023