aniling
accelerating epigenomics

QUALITY POLICY

Aniling aims to enable genetic analysis to make a significant contribution to precision medicine, specifically by accelerating the field of epigenomics.

The Management has established this Quality Policy with a view to guiding Aniling towards meeting the requirements and goals necessary to ensure customer satisfaction and meeting the legal requirements of its medical devices and services.

The Management expresses its commitment to the quality and regulatory requirements applicable to Aniling and encourages the proactive contribution of the staff in order to guarantee the effectiveness of the Quality Management System.

The quality of the Aniling's medical devices and services is ensured by a Quality Management System in accordance with:

- The UNE-EN-ISO 13485:2016 standard which specifies requirements for a quality management system where an organisation needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.
- The Directive 98/79/CE on in vitro diagnostic medical devices.
- The Regulation (EU) 2017/746 on in vitro diagnostic medical devices, repealing the Directive 98/79/EC and the Commission Decision 2010/227/EU .

This Quality Policy provides a framework to establish, review and achieve the Aniling's quality objectives with a focus on the following actions:

- The identification of the needs and expectations of the customers to define their specific requirements and ensure the provision of adequate, safe, reliable and compliant medical devices and services.
- The compliance with the applicable quality and regulatory requirements.
- The continuous monitoring to identify deviations and measure the effectiveness of Aniling's activities.
- The pursuit of excellence by identifying opportunities for improvement and optimization, by guiding efforts to control and correct the non-conformities as well as prevent their causes through an efficient CAPA process.
- The maintenance of the right conditions in the different areas of work of the company to ensure the safety of the staff, as well as the respect of the environment.

- The provision of safe and service-friendly material for the personnel to ensure the highest standard of quality for the medical devices manufactured.
- The review of the proposed objectives and related indicators.
- The provision of the necessary resources and means by the Management.
- The provision of the relevant training to all personnel dealing with quality processes to guarantee the necessary skills and competency in the execution of their functions.
- The guarantee of highest IT security for our data processing activities.

The Management ensures that the Quality Policy is communicated and understood throughout Aniling, as well as its continuous update after a periodical and thorough review of all of the applicable quality and regulatory requirements. Moreover, a Quality Assurance and Regulatory Affairs Manager who reports directly to the Management has been designated to ensure the compliance of this Quality Policy and the achievement of the Aniling's quality objectives.

The Management is convinced that the application of this Quality Policy will guide Aniling to success.

In Badalona, 19th of January 2023

Llorenç Coll
Chief Executive Officer
Aniling SL