

Sanymed is a company with over ten years of experience, engaged in the design, production and marketing of in vitro diagnostic medical devices (IVD) and medical-scientific equipment, intended for clinical and laboratory applications, with particular attention to population-level screening and diagnosis activities.

Our mission is to offer innovative, safe and clinically effective diagnostic solutions that contribute concretely to improving public health. In this context, the safety and health of end users, as well as the diagnostic efficacy of our products with respect to their intended use, represent the founding principles of our activity.

This Policy is appropriate to the nature and purposes of Sanymed, takes into account the internal and external context, supports the company's strategic directions and is consistent with the organization's desire to position itself as a reliable and competitive player in the IVD sector, both nationally and internationally.

Management Commitments

The Management of Sanymed is committed to:

- **Meet all applicable requirements**, including regulatory (EU Regulation 2017/746), regulators, customers and other interested parties;
- **Ensure that IVD devices are safe, performant and compliant with their intended use**, providing reliable results to support clinical and healthcare decisions;
- **Maintain and constantly improve the effectiveness of the Quality Management System**, in compliance with UNI EN ISO 13485 and UNI EN ISO 9001 standards, adopting an approach based on risk, traceability and objective evidence;
- **Promote continuous improvement**, through process review, proactive management of non-conformities, data analysis and active involvement of staff;
- **Provide adequate resources** and ensure an organizational environment oriented towards awareness, technical competence and quality.

Quality objectives

This Policy provides a framework for defining and reviewing corporate quality objectives, which are designed to guide Sanymed towards:

- achieving the highest quality of products;
- customer satisfaction;
- sustainable growth in international markets.

Three-year objectives (2025–2027)

1. Customer loyalty

- Maintain a satisfaction level of $\geq 90\%$ in the evaluations received via customer questionnaires.
- Maintain the number of customer reports ≤ 2 per year, through improved production control and QMS.

2. Expansion on the international market

- Increase international market share by 20% in 3 years.
- Obtain CE certification in the main European markets and expand the product portfolio in non-EU markets, in compliance with local regulations.

3. Compliance with Regulation (EU) 2017/746

- Complete the IVDR certification process within the established timeframes.
- Ensure 100% of devices comply with regulatory, safety and performance requirements, with full traceability throughout the product lifecycle.

Communication, engagement and empowerment

Sanymed promotes a corporate culture oriented towards quality and responsibility. To this end:

- This Policy is communicated, understood and shared at all levels of the organization;
- Continuous training and professional development activities are carried out to increase skills and strengthen awareness of individual and collective responsibilities;
- Active participation of employees in improvement processes and reporting of critical issues is encouraged.

Continuous review and improvement

The Management ensures the periodic review of the Quality Policy, during the Management Review, to evaluate:

- suitability with respect to the strategic context and regulatory developments;
- appropriateness with respect to business objectives and the needs of interested parties;
- effectiveness as an operational and managerial guide for achieving results.

Conclusion

Through this Quality Policy, Sanymed reaffirms its concrete, responsible and strategic commitment towards:

- the safety and effectiveness of their IVD devices;
- full regulatory and legislative compliance;
- customer satisfaction;
- sustainable international growth;
- the continuous improvement of its Quality Management System.

Signature:

