

## Quality Policy

**Since 1978, GIESSE DIAGNOSTICS S.r.l.** has been operating in the field of production and marketing of in vitro diagnostic reagents, providing reliable, high-quality solutions.



Its well-established presence in national and international markets, supported by a qualified sales network, represents concrete confirmation of the Company's reliability and of the quality of the products offered to customers.



As a manufacturer of In Vitro Diagnostic Medical Devices, GIESSE DIAGNOSTICS S.r.l. operates in compliance with Directive 98/79/EC, Italian Legislative Decree No. 332 of 8 September 2000, and Regulation (EU) 2017/746 (IVDR), for the applicable parts.



Management considers quality, safety, and regulatory compliance to be fundamental elements in ensuring reliable and consistently high-performing products over time.

### →Quality Commitments and Objectives

The Management of GIESSE DIAGNOSTICS S.r.l. is committed to:

- Obtaining and maintaining certification of the Quality Management System in accordance with ISO 9001 and ISO 13485 standards;
- Complying with all applicable mandatory laws and regulations, including those relating to worker safety and the safety of in vitro diagnostic medical devices;
- Ensuring compliance with the essential requirements set out in Annex I of Legislative Decree No. 332/2000, Directive 98/79/EC, and Regulation (EU) 2017/746;
- Ensuring product functionality, safety, and performance, in compliance with the Common Specifications, MDCG (Medical Device Coordination Group) guidelines, and applicable requirements;
- Adopting a defect-prevention-oriented approach, prioritizing process control over corrective actions taken after the fact;
- Monitoring and evaluating customer feedback related to the products and services provided;
- Carrying out assessments of business risks and opportunities in order to continuously improve the effectiveness of the Quality Management System;

- Periodically analysing customer and market needs, promoting innovation and continuous improvement.

To achieve these objectives, GIESSE DIAGNOSTICS S.r.l. continuously invests in research and development, ongoing staff training, and the careful selection, qualification, and evaluation of suppliers.

Management promotes a shared culture of quality, supporting all personnel in the application of the Quality Management System procedures and encouraging the active contribution of each individual to continuous improvement.

Customer satisfaction and product safety constitute the foundation of the relationships of trust that GIESSE DIAGNOSTICS S.r.l. builds every day with its partners and customers.

IL DIRETTORE GENERALE

