

# Quality Policy

Arrow Diagnostics S.r.l., founded in Genova in 2003, is a company specialized in the manufacturing of in vitro diagnostic devices (IVD) and the distribution of in vitro diagnostic devices and molecular diagnostics instruments.

The Company operates in the field of in vitro molecular diagnostics and is present nationally with a wide range of high-tech products, mainly reagents for the extraction and amplification of nucleic acids using PCR (PCR, RT-PCR, real-time PCR) and Next Generation Sequencing (NGS) techniques, under its own brand, under the brand of the parent company Seegene Inc. and third parties.

Arrow Diagnostics S.r.l. operates under a Quality and Integrated Management System compliant with UNI EN ISO 9001:2015, UNI CEI EN ISO 13485:2016, UNI CEI EN ISO 13485:2021 standards and European Regulations 2017/746 (IVDR) and 2024/1860 in order to ensure maximum customer satisfaction and stakeholder recognition, in full compliance with current regulations and laws.

The Senior Management of Arrow Diagnostics S.r.l. establishes the Quality Policy, undertaking to review it during the Management Review and to confirm or update it as required.

Research and development, business development, manufacturing, marketing, distribution, logistics, technical-scientific support and after-sales supervision, for all products placed on the market and the technical support services offered, comply with the Quality Policy, the main principles of which are the following:

- Maintain an effective Quality and Integrated Management System, through continuous improvement, in compliance with the UNI EN ISO 9001:2015, UNI CEI EN ISO 13485:2016 and UNI CEI EN ISO 13485:2021 standards;
- Apply and comply with the applicable requirements of European Regulations 2017/746 (IVDR) and 2024/1860;
- Interact with the relevant authorities in order to ensure market surveillance of own-brand in vitro diagnostic devices;
- Optimize the manufacturing of own-brand diagnostic devices and the distribution of products and services of the parent company Seegene Inc. and the other companies represented, respecting the production times and ensuring fast delivery times.
- Provide products and services that meet all applicable requirements, in compliance with industry regulations and the parent company's guidelines.
- Develop and maintain a Quality and Integrated Management System using a process approach based on Risk Management. Arrow Diagnostics identifies its main processes and undertakes constantly to improve them by defining the objectives to be pursued and continuously monitoring the results, establishing the related responsibilities and resources used; identifying, assessing and mitigating the associated risks and identifying opportunities;
- Focus every activity on the customer's needs and expectations, in order to ensure their full satisfaction in compliance with the relevant market requirements, the regulations enforced by the territories where the company operates and by all the parties involved in its business processes, constantly monitoring support and after-sales activities with adequate tools;
- Guarantee the operational continuity of the products and services provided through constant risk assessment;
- Promote appropriate culture and methodologies in the organization so that human resources are able to create the best devices in line with customer expectations and regulatory requirements, ensuring the constant training of its staff and keeping all the equipment used constantly monitored and maintained;
- Adopt a Risk Management System in order to encourage appropriate responsible behaviours that is attentive to device safety, work hygiene, environmental protection and information security.
- Prevent administrative violations by Directors, employees and contractors by implementing an appropriate Organisational Model, and disseminating the Code of Ethics/Conduct to the intended recipients, together with adequate training/information, and supervising its application.
- Constantly improve the performance of its Quality and Integrated Management System, establishing the following macro-objectives:
  - Fully comply with all quality regulations in all product sectors and markets in which the company operates, starting from research and development;
  - Improve customer satisfaction by ensuring a steady reduction in the number of complaints and an increasingly punctual and efficient service;
  - Respect the quality improvement and risk reduction plans associated with critical business processes;
  - Ensure maximum protection of the safety of its staff, its own-brand products, the products marketed and information management.

These macro-objectives, and the results achieved, are regularly reviewed by Arrow Diagnostics to determine their relevance and their compatibility with the context and the Company's strategic guidelines.

For this purpose, the Management of Arrow Diagnostics S.r.l. is committed to ensuring that this policy is understood, implemented and supported by all staff at all levels.

Every Arrow Diagnostics employee is responsible for maintaining and improving our Quality and Integrated Management System, making a fundamental contribution to achieving the Quality Objectives through effective daily actions.

The Quality Policy is published on the [www.arrowdiagnostics.it](http://www.arrowdiagnostics.it) website, made available to interested parties and communicated to all company personnel.

Genova, 26/11/2025

**ARROW DIAGNOSTICS SRL**  
The President  
Via Pietro Chiesa, 9  
16149 Genova - Tel. 010.6671796  
Part. IVA 01383850995  
Mod. POL01.01-05