

Quality Policy

Arrow Diagnostics S.r.l., founded in Genoa in 2003, is a company specialized in the realization of in vitro diagnostic kits (IVD) and the distribution of in vitro diagnostic reagents and molecular diagnostics instruments.

It represents world-renowned multinational companies in the in vitro molecular diagnostics sector and operates across Italy with a wide range of high-tech products, mainly reagents for nucleic acid extraction and amplification using Real Time (PCR, RT-PCR) and New Generation System (NGS) techniques.

Arrow Diagnostics S.r.l. operates according to a Quality Management System compliant with UNI EN ISO 9001:2015, UNI CEI EN ISO 13485:2016, UNI CEI EN ISO 13485:2021 and European Regulation 2017/746 (IVDR) in order to ensure the maximum satisfaction and loyalty of our Customers and recognition by our Stakeholders, in full compliance with current regulations and laws.

The 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, both internal and by qualified suppliers, 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 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 Regulation 2017/746 (IVDR);
- Interact with the relevant authorities in order to ensure market surveillance of own-brand in vitro diagnostic devices;
- Optimise the production of own-brand diagnostic kits 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 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;
- Disseminate an appropriate culture and procedures within the organisation to ensure that human resources are able to provide the best services and products in line with customer expectations, ensuring 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 behaviour that is attentive to safety, work hygiene, product safety, environmental protection and information security.
- Prevent administrative offences 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 Management System, establishing the following macro-objectives:
 - Comply fully 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 Management System, making a fundamental contribution to achieving the Quality Objectives through effective daily actions.

Genoa, 11.10.2022

The Chairman

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