



QUALITY AND SAFETY POLICY

ALIFAX, established in 1988, is a company certified EN ISO 13485: 2016/A11:2021, ISO 9001: 2015 and ISO 13485: 2016 MDSAP, which markets reagents and equipment for clinical analysis produced by third party companies, providing also technical assistance. Since 2015, through the merger with SIRE S.r.l. and since 2017, through the establishment of Alifax R&D, Alifax designs, manufactures, distributes and offers after-sales service for its own IVD medical devices.

The Management undertakes to:

1. Maintain the efficiency and effectiveness of the Company's Quality System in accordance with the requirements of ISO 9001:2015, ISO 13485:2016 and MDSAP.
2. Maintain, update and constantly improve the Company Quality System that ensures compliance with Regulations EU 2017/745 and 2017/746 in the most effective manner and in a manner proportionate to the risk class and type of device.
3. Comply with the regulatory requirements of the destination countries of the products, including, but not limited to, those adhering to the MDSAP scheme and to the European Union (Directive 98/79/EC and Regulations EU 2017/745 and 2017/746).
4. Manufacture and/or provide the Customer with innovative and safe products, meeting both the Customer's and any applicable regulatory requirements.
5. Grant the Customer care by satisfying his requests and resolving his complaints.
6. Within the Italian territory, guarantee the Customer a punctual delivery of the products.
7. Reduce costs by rationalizing production processes, waste and disservices in all company areas.
8. Guarantee appropriate information and staff training in order to maintain an effective and efficient Company Quality System.
9. Maintain, update and constantly improve the Company Quality System in compliance with Regulation (EU) 2021/821 related to the export control of dual use products.

The Management considers that the prerequisites for maintaining and further developing the aforementioned objectives are: Quality philosophy, environment respect and safety protection at workplace.

ALIFAX S.r.l.

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INSIDE INNOVATION

The Management shall be responsible for disseminating this Policy and review it periodically.

Polverara, 2025-02-20

The Management

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Iscritta al Registro delle imprese di Padova al n. 04337640280. Capitale sociale € 10.000.000 interamente versato.
Società con socio unico e soggetta all'attività di direzione e coordinamento di Alifax Holding S.p.A.

www.alifax.com