

Num	QP01		
Rev	05	Name	Quality Policy

CLINISCIENCES GROUP designs, manufactures, distributes and supports research and in vitro diagnostic (IVD) products, including software solutions, serving clinical laboratories, research institutions, hospitals, pharmaceutical companies and industry partners worldwide.

CLINISCIENCES GROUP is committed to delivering safe, effective and compliant products and services that meet applicable regulatory requirements and consistently satisfy customer and user needs.

Our Quality Policy is based on the following commitments:

Strategic product development

Develop products in alignment with evolving market needs in diagnostics, specific disease areas and research.

Customer and partner focus

Understand and meet customer, product manufacturer and distributor partner requirements, and continuously improve our products and services based on feedback and performance monitoring.

Regulatory compliance

Ensure compliance with applicable international and national regulations and standards for medical devices and IVDs, including ISO 13485:2016 and relevant regulatory frameworks (e.g. IVDR), throughout the product lifecycle.

Lifecycle and risk-based approach

Apply a risk-based approach to the design, manufacture, distribution and post-market activities of our products to ensure safety, performance and reliability.

Effective Quality Management System

Establish, maintain and continually improve an effective Quality Management System, supported by measurable objectives, performance indicators and data-driven decision making.

People and culture of quality

Promote a culture of quality by ensuring employee competence, awareness, engagement and accountability at all levels of the organization.

Top management is committed to providing the necessary resources to implement this policy, achieve quality objectives and maintain the effectiveness and certification of the Quality Management System.

This Quality Policy is communicated, understood and applied throughout the organization and is regularly reviewed during Management Reviews to ensure its continued suitability, adequacy and alignment with the Group's strategy and regulatory obligations.



Tushendan RASIAH
CEO of CliniSciences Group