# IVD BY KYMANOX
# IN VITRO DIAGNOSTICS IN FOCUS

**Advancing your IVD Medical Devices with collaborative and innovative solutions that are based on deep subject matter expertise and current regulations.**

## IVD MEDICAL DEVICE PRODUCT DEVELOPMENT

At Kymanox, we have a proven track record of providing solutions for in vitro diagnostic (IVD) medical device product development and registration in the EU and US. We partner with you and your team to develop strategic solutions to address the specific short-term and long-term needs of your product. We provide support throughout the product development life cycle, integrating your internal organization, development partners, suppliers, regulatory agencies, and Notified Bodies.

## EXPERTISE

The Kymanox IVD Medical Device team can assist you in evaluating your quality system to seamlessly achieve compliance with global design control and risk management requirements, saving you from costly delays and deviations. Below is a listing of how our team can support you:

- **Regulatory Strategies:** We develop robust regulatory strategies for your new product, or for expanding to new markets (e.g., FDA, IVDR, ROW).
- **Tailored Technical Documentation:** We expertly establish technical documentation aligned with your established processes, ensuring accuracy and efficiency.
- **Risk Management:** We provide comprehensive support in the implementation of ISO 14971 and harmonization of the risk management process within the context of the new In Vitro Diagnostic Regulations (IVDR) frameworks.
- **Clinical Evidence:** We assist in defining the clinical performance, conducting clinical evaluations, and managing post-marketing clinical follow-up for your device, ensuring compliance and efficacy.
- **Supplier Management:** We audit and manage your suppliers and establish seamless processes that integrate with your quality system.
- **Quality and Lifecycle Management:** We streamline your operations with audit ready QMS and technical documentation managed by advanced software tools.
    - We offer an effective design control and risk management lifecycle solution to enhance productivity.
    - We support the implementation of other tools available on the market.

# IVD BY KYMANOX
# IN VITRO DIAGNOSTICS IN FOCUS

## SUPPORT

**At Kymanox, we provide guidance and support for current industry practices and regulations, particularly:**

- ISO 14971 Risk Management
- IEC 62366 Usability Engineering
- ISO 20916 Clinical Performance Studies
- CLSI Standards and MDCG Guidance
- ISO 18113, ISO 20417 Labelling
- ISO 13485, ISO 9001 Quality Management Systems
- IEC 60601 Medical Electrical Equipment
- IEC 62304 Software Life Cycle Processes

**We provide guidance, leadership, and tactical support in the following areas:**

- Device and Process Development
- Design and Development Planning
- Assays and Reagents Development
- Companion Diagnostics (CDx) (co-)Development
- Technical Project Management
- Quality Management System Implementation and Integration
- Design Controls, Requirements Engineering, Verification and Validation
- Oversight of Software Development and Cybersecurity Requirements
- Assay, Software, and Hardware System Integration
- Design Transfer and Process Engineering
- Clinical Evidence, Performance Evaluation and Performance Studies
- Risk Management and Risk Analysis Techniques (PHA, FTA, FMEA)
- Human Factors Studies and Third-Party Laboratory Testing
- Design History File and Device Master Record
- Equipment Selection and Qualification
- Supplier Selection, Auditing, and Management
- Post-Market Surveillance, Vigilance and Market Surveillance
- Landscape Assessment of Competitive Products

Kymanox
Your Life Science Solutions Partner
Bio | Pharma | Device | Combo

Agilis by Kymanox | anteris by Kymanox | NEUMA by Kymanox