

AI-Driven Software in IVDs

Navigating SaMD Under the IVDR Today and Tomorrow

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Introduction: From Innovation to Oversight

Historically, software was a mere supporting tool for in vitro diagnostics (IVDs). Fast forward to today, it has become the modus operandi, the engine powering analysis, genomic interpretation, and wider clinical decision support. This shift has been accelerated by Artificial intelligence (AI) enabling increasingly sophisticated models that can analyse complex datasets with performance beyond conventional algorithms.

Yet, as innovation deepens, so does regulatory complexity. Under the EU In Vitro Diagnostic Regulation (IVDR), manufacturers must now navigate a framework that recognizes software as a medical device (SaMD) while simultaneously addressing the unique nuances introduced by AI technologies.

Since the full application of the EU In Vitro Diagnostic Regulation (IVDR) in May 2022, manufacturers face a recalibrated set of expectations. While the regulation outlines requirements for classification, safety, performance evaluation, and post-market surveillance, applying these to AI-enabled diagnostics introduces new considerations – particularly around ensuring algorithms are unbiased, robust and trustworthy.

At BSI, we support manufacturers in their conformity journey to meet these requirements and standards and build evidence frameworks that support compliance. Our focus as the longest standing National Standards Body is driving regulatory excellence to uphold the quality, safety, and performance of medical devices.



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Software in IVDs: Context and Relevance

Software is now aiding critical diagnostic functions – from classifying tissue samples to interpreting genomic variants and supporting real-time critical clinical decisions. These tools typically operate alongside human expertise, strengthening efficacy, consistency and ultimately accuracy
.
As the transition to IVDR took full effect, software performing IVD functions became subject to a more structured regulatory framework. This shift brings increased scrutiny on how evidence is generated, maintained, and assessed across the product lifecycle placing greater emphasis on demonstrating analytical robustness, clinical relevance, and ongoing performance monitoring - all requirements that extend well beyond traditional hardware centric approaches.

For AI enabled systems particularly, increased emphasis is placed on demonstrating ongoing performance, managing algorithmic change, and ensuring that the systems outputs remain clinically valid and appropriately controlled throughout the device lifecycle.

Manufacturers must now consider not only what their software does, but how it is validated, integrated and continuously monitored within clinical environments.

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Regulatory Alignment Today

Software intended for IVD purposes must comply with rigorous requirements covering its development, validation, performance, risk management, and post-market lifecycle. While the regulation does not distinguish between different algorithm types or prescribe AI specific validation approaches, it places strong emphasis on demonstrating performance in line with state of the art, ensuring cybersecurity, and maintaining operability, compatibility, and lifecycle control.

Key considerations for manufacturers include:

Algorithm behaviour and change management

- While adaptive or continuously learning systems are typically not used in the IVD domain, all software, regardless of algorithm type, requires ongoing performance evaluation, post market surveillance, and robust change control.

Stand alone SaMD versus software embedded within an IVD system

- Whether software operates independently or as part of a wider device influences how manufacturers interpret classification and evidence expectations. Many organisations still face challenges determining whether their software meets the definition of an IVD in the first instance, reflecting areas of ambiguity in the current regulatory framework.

BSI's assessors respect these nuances. We support manufacturers globally in designing evidence strategies that are technically robust, clinically relevant, and operationally feasible.

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AI-Specific Challenges: Transparency, Adaptivity, and Trust

AI introduces considerations that extend beyond traditional software under the IVDR. While the regulation does not yet provide AI specific requirements s as in the EU AI Act, key areas of focus include:

Transparency and explainability

- Manufacturers must provide sufficient transparency to demonstrate how the system supports its intended purpose. This includes documenting training data characteristics, model behaviour, known limitations, and ensuring outputs are interpretable to users at a level appropriate to the device's risk.

Adaptivity and learning behaviour

- IVD algorithms typically remain fully locked post-deployment, and current challenges centre mainly on supporting manufacturers in validating newly developed algorithms, managing updates and ensuring that any changes remain fully controlled and reproducible.

Data quality, representativeness, and bias

- AI systems rely heavily on the quality and diversity of their training data. Under the IVDR's performance evaluation framework, manufacturers must demonstrate that datasets are appropriate for the intended purpose and that potential sources of bias have been assessed and mitigated to protect safety, equity, and clinical relevance.

Cybersecurity and interoperability

- AI enabled IVDs must integrate safely within laboratory and clinical environments. The IVDR requires manufacturers to address cybersecurity risks, ensure reliable data exchange, and demonstrate compatibility with the systems and workflows in which the device will operate.

At BSI we actively support manufacturers in navigating this space of complexity. With deep expertise in AI assurance, we provide guidance to manufacturers in validating newly developed algorithms, managing lifecycle risk, and building systems that are compliant, trustworthy and capable of delivering transformative clinical impact.



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Real-World Applications: AI in Practice

Digital pathology

- AI based image analysis tools can support the assessment of histopathology slides by identifying regions of interest, highlighting atypical features, and reducing inter observer variability. These systems aim to improve workflow efficiency and support consistent diagnostic interpretation and most AI-enabled pathology devices entering the market today are newly developed and undergoing IVDR conformity assessment instead of relying on IVDD transitional provisions.

Next-generation sequencing bioinformatics

- Automated variant calling pipelines use machine learning approaches to prioritise genomic variants, support interpretation, and assist in identifying potential therapeutic pathways. These tools help standardise analysis and reduce manual review burden in high throughput sequencing environments.

Nnear patient and decentralised diagnostics

- AI assisted interpretation of near patient tests such as automated reading of lateral flow assays, or digital analysis of rapid antigen or molecular near-patient tests are emerging to support rapid decision making in primary care and emergency settings. These applications sit within the broader IVD ecosystem and highlight the need for clear regulatory pathways as AI becomes integrated into decentralised diagnostic workflows.

Each use case demands thought, care and structured regulatory strategy. Aligning innovation with compliance is essential to ensure safety, maintain trust and enable responsible progress.

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Outlook: Anticipating Regulatory Evolution

The EU regulatory landscape for AI-enabled diagnostics has now taken a clearer shape. The EU AI Act introduces horizontal obligations for high-risk AI systems, including many diagnostic applications, and with the adoption of the AI Digital Omnibus, organizations now have a defined roadmap for compliance. The Omnibus has revised and confirmed key enforcement timelines, giving manufacturers greater certainty on when obligations will apply – including to AI systems embedded in products already governed by existing EU product safety legislation such as the IVDR. For organizations developing or deploying AI-enabled diagnostics, the path forward is one of dual compliance: meeting both IVDR requirements and the structured AI governance obligations that now form part of the wider regulatory framework.

This means that organizations operating in the in vitro diagnostic space are well-positioned to get ahead of the curve. The convergence of sector-specific In Vitro Diagnostic Regulation (IVDR) requirements with emerging AI governance standards is driving a more structured, transparent approach to AI regulation – and international initiatives such as the International Medical Device Regulators Forum (IMDRF) and the FDA's Good Machine Learning Practices are accelerating that shift. For organizations that act now, aligning with both frameworks represents an opportunity to build stronger governance, demonstrate regulatory readiness and establish a credible position in an increasingly well-regulated market.

These developments mark a new phase of regulatory design shaped by collaboration, adaptability, and evidence strategies that evolve with the technology.



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Conclusion: Enabling Responsible Innovation

AI-enabled diagnostics demand regulatory clarity, clinical relevance, and public trust. At BSI, we offer structured, expert-led assessment at the intersection of software, AI, and IVD regulation. We support innovators from concept to market and beyond, helping them build systems that are compliant, credible, and market ready.

Advancement means clarifying the path forward. As the UK's first standards institution and a leading Notified Body. Our mission at BSI is to align innovation seamlessly with global and local compliance, governance, safety and performance requirements. We support manufacturers worldwide to build the future of in vitro diagnostics - for today's technologies and those to come.

When you work with BSI's in vitro diagnostic (IVD) team, you're working with the world's leading IVD Notified Body team of experts. With more than 650 cumulative years of industry experience and over 215 years of Notified Body experience, our globally distributed team of senior scientific, clinical, regulatory and industry specialists bring deep scientific credibility, hands-on practical knowledge and recognized Notified Body authority together in one place.

From molecular diagnostics and immunoassays to software and AI-enabled IVD systems, our expertise spans the full breadth of the IVD landscape - enabling end-to-end conformity assessment throughout your device's life cycle, from early development and performance evaluation through to IVDR certification and post-market surveillance.

With pan-European and international regulatory insight, multilingual capability and local presence across global markets, BSI supports you with structured and trusted conformity assessment - helping your products reach and remain on the market with confidence.

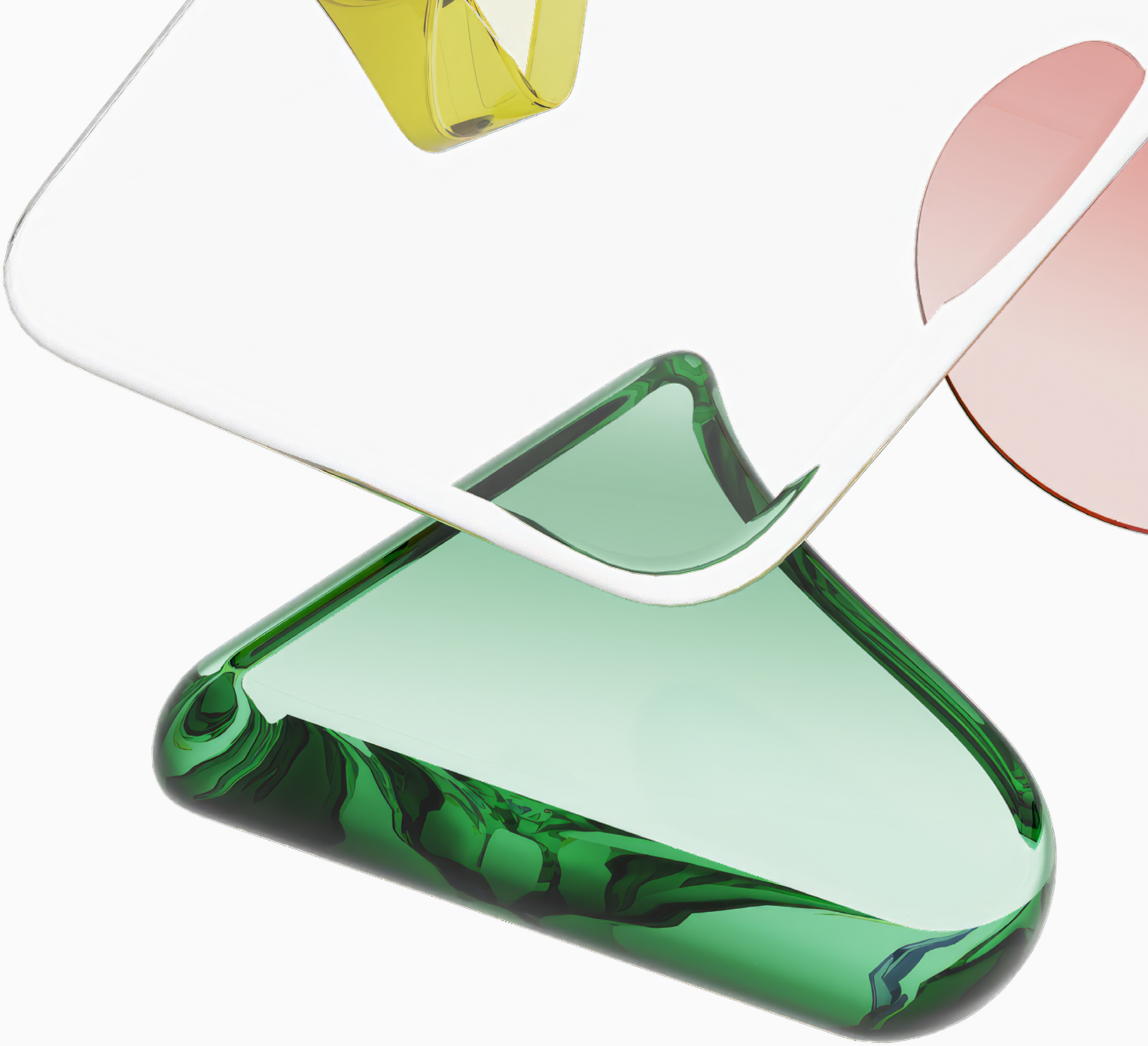


About the Author

Hedele Pitman, BSc (Hons), PhD, is a Technical Specialist & Scheme Manager for IVDs at BSI. Hedele joined BSI in 2023 after spending 10 years as an R&D scientist at Leica Biosystems, an IVD manufacturer specialising in cancer diagnostic products for pathology laboratories and workflow solutions. During her time at Leica, Hedele developed a range of IVDs and companion diagnostic (CDx) devices, including CDx tools for breast and colon cancer. Her work involved close collaboration with pathologists, pharmaceutical partners, and digital pathology teams.

Before joining Leica, Hedele studied at Newcastle University in the UK, where she earned a BSc in Biochemistry and a PhD in reproductive immunology. Since becoming a Technical Specialist at BSI, Hedele has reviewed multiple AI-based cancer devices – primarily within digital pathology – as well as AI tools designed to predict prostate and breast cancer recurrence.

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