How To Ensure Full IVDR Compliance On Time

A White Paper from Kallik

KALLIK

Compliance rises up the business agenda as medical regulation continues at pace

The European Union's In Vitro Diagnostic Regulation (IVDR), set to be implemented for critical in vitro devices used to detect life-threatening diseases in May 2023, is the latest significant compliance challenge to manufacturers and the industry. IVDR is intended to enhance the safety, effectiveness and traceability of all in vitro devices currently sold or intended for sale in the EU market, stipulating that product label and artwork be updated accordingly.

IVDR replaces the previous longstanding In Vitro Diagnostics Directive (IVDD), and makes major changes reshaping product classifications, quality management and how existing product already sold within the EU are managed. Over 80% of devices previously not requiring certification under IVDD now require IVDR certification. The new regulation is also intended to link closely with its 'sister' legislation, MDR (Medical Device Regulation), which focuses on the broader medical device sector. Manufacturers operating in both fields will have to respond to both sets of regulatory requirements in a relatively short timescale.

These demands – all falling against a backdrop of significant operational disruption caused by the COVID-19 pandemic – have placed compliance firmly at the top of the agenda for manufacturers and their supply chains. The timeline for MDR and IVDR compliance alone is extensive, with implementation dates for various phases spread across the decade – but business leaders should take note that further national and regional legislation, triggered by developments such as Brexit, is inevitable.

Timescales mean there is no time for complacency

Come May 2023, manufacturers of in vitro diagnostic devices will need to ensure the most critical Class D devices include the Unique Device Identifier (UDI) on their labeling and have the necessary artwork to demonstrate compliance. This deadline is quickly followed by May 2025 for Class B and C devices, and finally May 2027 for Class A – the lowest risk device category.

For those manufacturers that have already completed an initial project to comply with MDR by May 2021, it may be tempting to sit back and delay their IVDR efforts. Business disruption caused by the pandemic and the subsequent mass shift to remote operations, which prompted the EU to delay MDR implementation deadline by one year – may also have added to the belief among some business leaders that there is ample time remaining. But the scale of these compliance tasks and the wide-ranging impact regulation has on end-to-end operations and the supply chain is often underestimated, and only uncovered during the initial assessment stages of a compliance project.

Manufacturers must ensure they comply with every aspect of IVDR demands to avoid financial impact, operational disruption and permanent damage to brand reputation in the event of consumer harm caused by device quality or traceability issues.

With 2021 analyst research valuing the in vitro diagnostics market size at over $83 billion and projecting sustained annual growth, businesses who do not act now risk losing an opportunity to secure and expand their share of this lucrative global market.

Lessons to be learned from MDR experiences

At Kallik, we have extensive experience of working with organizations in highly regulated industries. In the label and artwork management (LAM) sphere of compliance, Kallik experts have been at the forefront of helping leading international businesses in the medical device sector ensure compliance in a timely and effective manner, adapting and enhancing existing LAM operations within narrow timeframes.

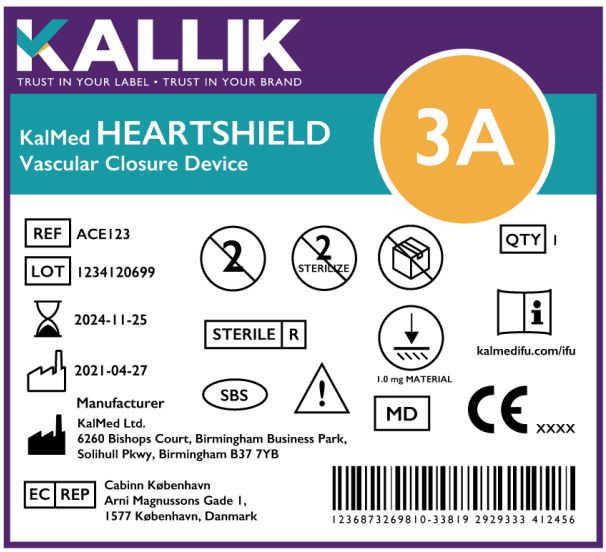
One of the key takeaways from successful projects helping medical device manufacturers to comply with MDR was the need to embrace a best practice approach. Companies that have opted to 'go it alone' and push ahead with compliance efforts using existing legacy processes and systems developed in-house have often struggled as the scale and complexity of the task becomes apparent.

This challenge is often amplified by complacency over project timeframes. For MDR, many companies have significantly underestimated the amount of time and effort required to achieve full compliance, even struggling despite the one-year Covid-19 extension. Indeed, Kallik experts have intensely worked with multiple medical device manufacturers to accelerate projects in the weeks leading up to the May 2021 deadline.

The volume of work and level of detail required must not be underestimated

There are many nuances to labeling under the new regulation, including significant differences between medical device and in vitro device artwork and major design changes to layouts to accommodate increased traceability information. This combination of challenges makes a fit-for-purpose label and artwork management solution, powered by automation, a necessity.

The sheer volume of work entailed means that medical device companies that embrace IVDR compliance as a business priority and develop plans to achieve this as early as possible will stand a greater chance of succeeding without incurring major expense or affecting day-to-day operations. Organizations that delay compliance projects in favour of maintaining the status quo will see timeframes narrow from years to months – making large-scale changes to operations infeasible and running the risk of incurring significant business damage.



Charting a path to compliance

Medical device manufacturers will need to establish and execute a plan to deliver full compliance ahead of the planned deadline, ranging from initial assessments to identify affected assets and project scale, processing label changes to satisfy new requirements and deploying fit-for-purpose technology to manage IVDR-compliant operations.

This must also be achieved in a timely manner, without affecting day-to-day business or diverting excessive amount of capacity from standard workloads. IVDR compliance projects will be large-scale by nature due to the sheer volume of devices and associated labeling involved – but there is also a unique opportunity to build on this by conducting a full-scale review of operations, identifying areas ripe for technology transformation and process improvements.

There are four core components for businesses working towards IVDR compliance:

1. Assessing the scale of the task is no easy matter

Kallik has worked with medical manufacturers that have been compelled to make changes to over 150,000 assets to reach MDR compliance once initial assessments have been completed – so the volume of work to be done must not be underestimated.

Organizations must get to grips with the scale of their compliance task as early as possible. Businesses still in the planning and pre-planning stages of their IVDR project will need to identify exactly how many devices and associated labels and artworks exist across their global operations and supply chain.

Hidden in silos?

Siloed data in legacy systems, disconnected regional offices and departments and scattered assets are all hidden threats to compliance that can significantly expand the scope and timeframe of the project.

Global supply chain adds translation complexities

Product translations and global supply chains are also common yet often unexpected force multipliers when assessing the complexity of a compliance project. Internationally focused businesses will need to amend numerous language variants of each label and packaging item, significantly increasing the scale of work. Amending individual phrase translations on each device in a product range, for each of the EU's 24 official languages, threatens to add significant cost and time to successful compliance.

M&As on the cards? Make sure you add to the plan

Looking beyond this, mergers and acquisitions are a common occurrence within the medical device industry and act as another challenge to compliance, introducing new product lines, data silos and asset libraries that instantly add further burdens to ongoing compliance projects.

2. Consolidate and standardize assets

Identifying every silo containing global assets is a first step on the compliance path, yet before actioning label and artwork changes, businesses should look to consolidate all assets into a single central source. Attempting to manage editing, review and approvals processes across multiple systems and departments is both highly inefficient and runs the risk of introducing costly version errors and delaying the compliance process.

Take the pain away with a label and artwork management solution

Business leaders still getting up to speed in the compliance deadline race would be well-placed to adopt an off-the-shelf label and artwork management solution that incorporates a single, centralized asset library to contain artwork, logos, phrases and other critical product data. Many LAM providers offer automated capabilities to aid with the extraction of content from data silos and legacy systems, including supporting the subsequent standardization and loading of data into the new LAM solution.

Consolidating all assets into a 'single source of truth' significantly eases the monitoring, editing and management burdens when compared to attempting to do so across multiple systems and geographies. Once all artwork and assets are contained within this library, businesses can focus solely on dedicated compliance work through label editing without needing to continually identify, gather and share assets for each amendment.

3. Drilling down to identify the regulatory impact

Once existing assets have been consolidated and all relevant data standardized, businesses can begin to look at the specific changes that must be made to each label and artwork to achieve compliance.

There are many factors to consider here from label sizing and placement, to warning symbol positioning and Unique Device Identifier (UDI) inclusion – and these can be further complicated by translations and specific national requirements.

This is another situation where the consolidation of assets into a single LAM solution yields dividends. The Kallik Veraciti™ platform, for example, provides a powerful 'Where Used' feature that enables users to rapidly identify all labels affected by a minor design change and take action accordingly. Combining this capability with approved label templates within the LAM solution means users can effortlessly make changes to all labels in a product range – eliminating the need to manually identify and update each asset impacted by IVDR changes.

4. Deploy automation at the heart of operations

As many businesses experienced during the initial MDR May 2021 compliance push, relying purely on 'traditional' methods and updating assets through manual work and processes becomes increasingly unviable. These have been found to be typically slow, costly and have the continuous underlying risk of introducing inaccuracies through human error.

Springboard for future efficiencies

The compliance push to May 2021 also highlighted the realization that global labeling operations are in need of a modernization, which has meant a significant addition to the existing IVDR burden – often requiring the hiring of extra staff or diversion of existing resources to meet deadlines. As we can see, this need not be the case. Modern LAM solutions offer a greater amount of automation and more importantly, the potential for future efficiencies through for example AI integration.

Automated label and artwork management solutions represent a well-integrated, future-proof alternative to outdated manual processes and legacy systems – many of which have been developed in-house to fulfil niche requirements and are of limited use in aiding a modern compliance push. Automated artwork generation, for example, avoids reliance on third-party designers and is capable of creating medical device artwork in as little as 12 seconds.

Introducing a cloud-based, centralized solution with a high degree of automation eliminates the uncertainty of manual processes. The result is an efficient operation, following best-practice procedures, providing a certain outcome. Such solutions harness rules-based automation to eliminate the need to manually search for, update and republish assets to ensure compliance, and deliver significant cost and capacity savings that scale over time.

Prepare for a heavily regulated future with effective LAM

While IVDR is a fundamental change to the way medical device operators do business and requires a significant push to achieve compliance, this also represents a perfect opportunity to get ahead of the regulatory curve and avoid continually playing catch-up with new industry requirements.

Assets that have been updated to comply with IVDR will very likely be affected by further regulatory change – potentially at both a national and regional level. MDR and IVDR will both see phased implementation for various device classifications throughout the decade, and further changes such as UKCA markings for medical devices sold into the UK market are also in the works.

Medical device manufacturers that act now and move ahead of the current regulatory pipeline will be best-placed to plan and comply with each new wave of legislation. Those businesses that struggled to find the time and capacity to manually meet a single deadline will continue to play catch-up with the industry as future regulations arrive – especially if their business, product range and asset libraries continue to grow.

This is why it is critical manufacturers seize the opportunity to deploy an end-to-end LAM solution capable of handling large-scale compliance tasks and containing the features necessary to make stipulated changes – shifting compliance work from a last-minute, reactive process to a proactive strategy.

Get ahead – and stay ahead – of the regulatory curve

IVDR implementation is an inevitability – but one that medical device manufacturers are still very much in control of. Acting early to establish a best practice compliance plan that includes root-and-branch review of global operations and technology-driven asset consolidation and management will put businesses firmly in the driving seat ahead of the initial May 2023 deadline.

With the phased implementation of both MDR and IVDR underway, it has become apparent that manufacturers will experience significant challenges attempting to deliver and maintain compliance through manual processes. Acting now to implement automated LAM solutions will enable businesses to both benefit from continuous process and efficiency improvements and establish a framework for rapid regulatory compliance.

End-to-end, cloud-based LAM solutions such as Veraciti from Kallik offer an ideal solution to bring comprehensive visibility, control and traceability to global labeling operations. Storing all labeling, artwork and data in a centralized repository eliminates the common challenge of information silos from both day-to-day operations and targeted compliance projects, providing full audit trails and powerful capabilities such as automated artwork generation.

In vitro diagnostic device manufacturers still have time to both begin their IVDR compliance push and make steps to transform their label and artwork management with automation, but it is vital action is taken soon. Establishing a strong digital foundation today will help business leaders establish a long-term compliance strategy and seamlessly execute this using advanced technology, while continually benefiting from the broader improvements brought by deploying a LAM solution to underpin business operations.

About Kallik

Kallik, the enterprise labeling company, provides regulated industries with a responsive, end-to-end label management platform they can trust.

Its cloud-based labeling platform, Veraciti™, delivers definitive compliance and supply chain efficiency for all the content assets that make up product packaging, labeling and customer information documents. From barcodes to safety symbols and text, Veraciti manages any format, in any territory, on any material and via any channel - with complete reliability and traceability.

Medical device manufacturers, pharmaceutical firms, chemical and cosmetics companies use Kallik to deliver trust in their labeling, confidence in their brand and integrity in their process.

To find out how we can support label and artwork management transformation in your business, please get in touch by emailing us at enquiries@kallik.com.