Don’t Fall Short with New EU MDR Deadline

Does Your Labeling and Artwork Offer a Path to Compliance?

Loftware™

White Paper

The road to implementation of the European Union's Medical Device Regulation (EU MDR) has indeed been a long and arduous one. Originally medical device manufacturers were expected to recertify their MDD (Medical Devices Directive) products under the EU MDR regime by May 2024. Alongside this, there has been increasing concerns that many products certified under the previous regime were to be withdrawn from the market, as companies have struggled to justify the costs of recertification and ongoing compliance which includes more complex labeling protocols. Put simply, this market response could be disastrous for patients in the EU who could find themselves not only missing out on medical device innovations, but also losing access to trusted products that have been saving lives for decades. This decision is literally a matter of life or death and patient safety.

With a continued shortage of notified bodies causing major hurdles for medical device manufacturers' preparedness, along with pressure and critical concern for patient safety, EU MDR transitional periods were finally extended.

In February 2023[1] in an overwhelming majority vote of 537-3, the European Parliament recognized the critical need to mitigate the risk of shortages for patient safety by granting an extension for the new EU MDR to 2027 or 2028 depending on device's risk class. High-risk devices would be subject to a shorter transition period ending in 2027, while low- and medium-risk devices would have until the end of 2028 to complete a conformity assessment. This passage will allow medical device manufacturers who didn't have the time or resources to become EU MDR compliant to reconsider if selling in the EU is a viable option, and can now take advantage of this opportunity to properly and cost-effectively implement labeling solutions that offer a clear corridor to compliance.

[1] https://www.raps.org/news-and-articles/news-articles/2023/2/european-parliament-votes-to-extend-mdr-transition

The path to EU MDR compliance

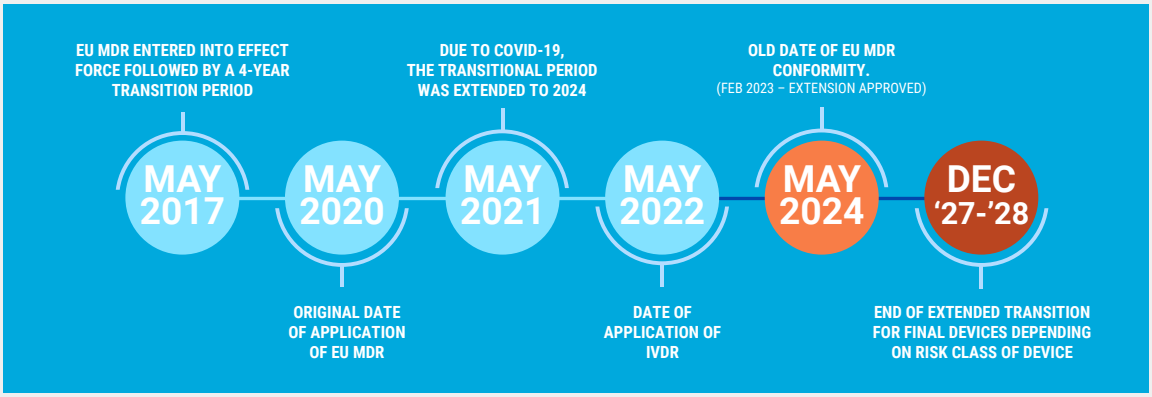
The new regulatory framework was approved by the European Parliament in April of 2017 to replace the previous MDD that had been introduced in the 1990s. The intention of EU MDR is to make a complete overhaul of the legal regulations for medical devices and improve patient and user safety while allowing for the effective functioning of an internal market for medical device products. EU MDR entered into force in May of 2017 and became applicable on May 26, 2021, followed by a postponement to May 2024 to allow authorities and manufacturers the ability to prioritize in response to the COVID-19 pandemic.

According to the EU Commission, extending the transition period would not compromise patient safety. "The application of the extended transition periods will be subject to several cumulative conditions, in order to ensure that only devices that are safe and for which manufacturers have already taken steps to transition to the Medical Devices Regulation will benefit from the additional time," the Commission said, pointing to the COVID-19 pandemic, supply chain disruptions, notified body capacity and economic operator preparedness as factors necessitating the delay.

The proposal comes one month after members of the European Council expressed support for delaying the EU MDR transition period. In a meeting before the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) in Brussels on December 9, 2022, European Health Commissioner Stella Kyriakides recommended the delay given the multiple issues putting a "strain on market readiness."

The EU MDR is complemented by the In Vitro Diagnostic Regulation (IVDR) which became applicable on May 26, 2022, marking the start of a staggered extension of its transition period for manufacturers and economic operators. Both EU MDR and IVDR were created to meet the constantly evolving technological and scientific progress requirements for medical devices. With more than 500,000 types of medical devices on the market, the EU MDR has paved the way to supplying a more patient-focused approach to regulations. The approval of an extended transitional period was a clear effort to help prevent device shortages and help companies meet the need for innovative, high-performing devices and new therapies.

EU MDR TIMELINE



Why is the EU concerned about medical device shortages?

At the heart of the EU MDR regulatory framework is a more rigorous system of conformity assessment. While already applied to new devices, EU MDR will also become applicable to all existing devices that remain on the market following the transitional period. A shortage of notified bodies has meant that medical device manufacturers have struggled to secure certification even when they have all the documentary evidence that is required.

In December 2022, Reuters spoke to several medical device manufacturers who were in the process of withdrawing their products from the EU market due to the burden posed by EU MDR[2], including devices that had been safely used by clinicians for decades. In the report, an executive at a small medical device manufacturer based in California explained that the excessive costs of recertification meant that it was simply not financially viable for the company to continue to supply niche products such as a tiny catheter used on newborns with heart issues in advance of surgery.

The effect of EU MDR on labeling

One of the biggest impacts on labeling is the requirement for the inclusion of Unique Device Identifiers (UDIs). EU MDR expands the international standard with the introduction of Basic-UDIs, allowing for the effective grouping of devices, with each Basic UDI-DI (Device Identifier) serving as a parent descriptor for a product family or category - this does not need to be printed on the product or its packaging.

The UDI of each product consists of two parts: UDI-DI and UDI-PI (Production Identifier). The former contains standard information about a device (name, version, number of uses, critical warning etc.), and a new UDI-DI needs to be issued should any of this change. UDI-PI holds more dynamic information, including the lot/batch number and expiry dates, consequently UDI-PIs change on a regular basis.

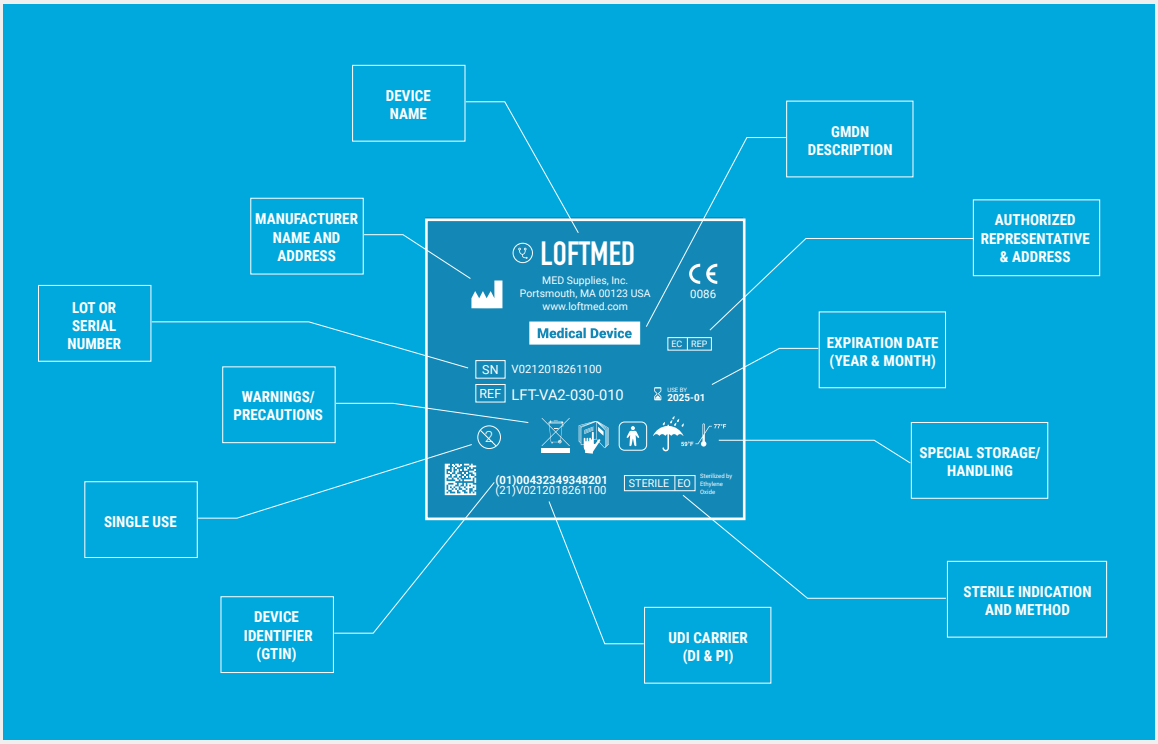
Finally, each level of packaging apart from shipping containers, needs to be labeled with its own UDI. i.e., A box containing a single device, a pack containing several boxed devices, and a case containing several packs of boxed devices, each need a unique UDI-DI and UDI-PI.

The inclusion of UDIs is just one of several mandatory EU MDR labeling criteria, including standard iconography and instructions on how to access eIFUs (Electronic Instructions For Use). As ever, labeling errors are likely to result in regulatory enforcement and costly product recalls.

[2] https://www.reuters.com/business/healthcare-pharmaceuticals/medical-device-makers-drop-products-eu-law-sows-chaos-2022-12-19/

With many medical device manufacturers having hundreds if not thousands of SKUs (Stock Keeping Units), each requiring a label, ensuring that each of these labels is EU MDR-compliant is a mammoth task. Indeed, if the company is using manual systems to manage its labels, then simply identifying which labels need to be updated is an incredibly daunting and time-consuming effort.

SAMPLE EU MDR LABEL



The impact of import and export on labeling

Without exceptions all products must adhere to cross-border regulations regardless of product industry. Importation and exportation of medical devices in particular adds more dynamics into the already murky waters of labeling medical devices as additional information needs to be included on their labels. With increasing business competition, it is the dream of every organization to venture into new and emerging markets. This comes with addressing complicated labeling and packaging challenges. The United States, the EU, and a host of other countries have many importation laws in place. To navigate these requirements, companies must establish more modernized comprehensive labeling solutions.

How to avoid recalls and non-compliance

Deloitte estimates that up to 15% of recalls involving medical devices are because of labeling errors. This is bound to increase once the new guidelines take effect. Apart from product recalls, other implications of non-compliance will include additional levies, fines, retention of shipments at border points, and loss of partnerships, among others. These operational repercussions may seem drastic but there is no option but to comply.

Failure to comply with labeling challenges outlined in EUDAMED (European Database on Medical Devices) will mean that several companies will fail to register or re-register their products. Indeed, this will lead to the loss of the European market or an interruption in the supply chain. EU MDR shares a lot with UDI and with the two in place, companies will have to review their existing labeling solutions to ensure they can meet all the ensuing labeling complexities. Otherwise, they will find that they could face big barriers that will render them with devices that will not see local or international markets.

Many companies continue to use error-prone manual labeling and artwork management systems that consist of disjointed applications and databases and lack accountability. Spreadsheets, legacy systems and even some software packages are simply not reliable enough to ensure compliance for the evolving demands of global medical device labeling. Ultimately, complex EU MDR requirements call for validated labeling solutions that enable dynamic, data-driven labeling, ensure security and auditability, and integrate with sources of truth in order to navigate any regulatory barriers.

There is currently no doubt that companies are aware that labeling is a mission-critical aspect of the supply chain. However, too few companies have the labeling and packaging artwork solutions in place that will guarantee regulatory compliance, efficiency, validation, brand consistency, responsiveness, customer satisfaction, and revenue.

Offering a path to EU MDR compliance

Recertification of products previously approved under the MDD regime has proven to be a costly endeavor with some companies poised to abandon the EU market despite millions of dollars of investment in their product portfolios. Without the means of streamlining and reducing the cost of EU MDR compliance, many life-saving devices could be prevented from aiding patients, even when they have a solid track record on the market. In the case of new products, it is an understandable temptation for some companies to ignore the EU and focus on scaling other markets like the USA instead.

Fortunately, however, the European Parliament recognized this critical need to mitigate the risk of shortages for patient safety by granting another extension for the new EU MDR to 2027 or 2028 depending on a medical device's risk class. This passage will allow manufacturers who felt they did not have the time or resources with the previous deadline to become EU MDR compliant to reconsider if selling in the EU is a viable option and can now take advantage of this opportunity to implement labeling solutions properly and cost-effectively. With this, the medical device and patient communities have been given an enormous gift with the EU MDR extension and companies **must not wait** to address labeling concerns. There is no guarantee that even by 2027 or 2028 the shortage of notified bodies will be resolved so medical device manufacturers need to act now.

Benefits of adopting an end-to-end validated labeling solution

With labeling, to ensure compliance manufacturers need to know that the correct identifiers are in the correct place, and to do that they must ensure that key data elements and formats are all reliable. With that in mind, manufacturers need an end-to-end validated labeling and packaging artwork solution, which provides access to centralized data, while providing audit tracking and security controls combined with workflow management and eSignature capabilities.

Businesses may have entities around the globe, but that does not mean that when it comes to labeling it should be "every entity for itself." Having centralized labeling brings end-to-end visibility and control—and the ability to demonstrate compliance—to headquarters. Also, labeling should enable remote manufacturing locations to local labeling requirements while ensuring compliance to corporate standards.

Automate, optimize, and centralize labeling

Organizations need to re-think legacy systems. Spreadsheets, legacy systems and even some labeling software packages are not reliable enough to ensure compliance for the evolving demands of medical device labeling. They also need a centralized, automated, and validated solution which can scale with their business to ensure compliance with evolving regional and international regulations.

Integrate with sources of truth

While spreadsheets or even desktop-based software products may offer a quick solution to a data problem, they were never intended to be sources of truth. The best practice for managing EU MDR and other labeling regulations is to replace disparate databases and manual processes with content management systems and other sources of data such as trusted enterprise systems, and other business applications that generate the data required for UDI and EU MDR.

Enable fast, flexible label changes

Design capabilities should be advanced enough to support the full gamut of labeling—from product to carton to shipping container—while enabling non-technical businesspeople involved in the regulatory process to create and manage their own label templates and business rules, without having to call on IT. This type of dynamic, data-driven labeling enables those users to quickly respond to a range of labeling variations including regional and international regulatory requirements. Validation is also streamlined when owners of label real estate can easily make mass label changes to specific areas of interest without having to revalidate the entire label.

Ensure security and auditability

A solution that provides full auditing and reporting capabilities, with business intelligence can monitor and track all labeling activity and create custom or preconfigured reports to meet regulatory needs. It is also important to ensure closed-loop workflow and approval processes for labels that include version control, commenting, support for EU MDR, UDI, 21 CFR Part 11 (US FDA checklist), and eSignatures.

How to futureproof your labeling

Medical device organizations need a solution that can easily support new languages, new market requirements, and quickly expand usage to be ready for future regulations. When dealing with translations, failure to produce accurate, EU MDR-compliant labels and other product information could necessitate a product recall or could even delay market entry. To avoid these risks, centralized translation management can fully support localization strategies. Therefore, it is important to think long-term and build solutions that flex as the regulatory environment evolves.

Finally, when it comes to managing medical device labeling, manufacturers need a solution that enables compliance with EU MDR, FDA UDI and 21 CFR Part 11 regulations and is designed to help enable expedited and streamlined validation. With Loftware, companies can keep pace with evolving EU MDR and other important regulations by quickly and easily making label changes to formats, barcodes, logos, languages, and content—including the addition of industry-specific warnings, product information, and even color to meet global and regional requirements.

For more information on how Loftware can help standardize and automate labeling and packaging across a global landscape and address pressing demands around EU MDR, please contact one of our Medical Device Industry Specialists. Don't wait to be up against the next deadline—learn more about how Loftware can help medical device manufacturers deliver EU MDR-compliant labeling here.

Loftware is the world's largest cloud-based Enterprise Labeling and Artwork Management provider, offering an end-to-end labeling solution platform for companies of all sizes. Maintaining a global presence with offices in the US, UK, Germany, Slovenia, China, and Singapore, Loftware boasts over 35 years of expertise in solving labeling challenges. We help companies improve accuracy, traceability and compliance while improving the quality, speed, and efficiency of their labeling. As the leading global provider of Enterprise Labeling and Artwork Management, along with Clinical Trials Labeling and Content Management, Loftware enables supply chain agility, supports evolving regulations, and optimizes business operations for a wide range of industries. These include automotive, chemicals, consumer products, electronics, food & beverage, manufacturing, medical device, pharmaceuticals, retail, and apparel.

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