NiceLabel®

Getting your labels ready for EU MDR:

Five steps to ensure your systems and processes are optimized for compliance

White Paper

Introduction

The date of application for the European Union Medical Device Regulation (EU MDR) is May 26, 2021. What do you need to know in order to be ready for the deadline? And how can you ensure that your labeling system and processes are MDR-ready? We've prepared this brief guide to help you on the path to EU MDR-compliant labeling.

The road to the new EU MDR

Before we talk about what the new rules mean for your labeling, let's take a look back at how we got here. In 2017, the European Commission announced the introduction of two new medical device regulations, which would replace the three existing medical device directives: the IVDMD[1], MDD[2] and AIMDD[3]. The existing directives date back to the 1990s, and the medical device sector has experienced significant technological and scientific developments since their inception. There have also been issues with differing interpretations of the existing directives amongst the 27 EU member states. And incidents involving medical devices, such as the PIP breast implant scandal, have highlighted weaknesses in the existing legal framework and safety protocols. The new framework will, it's believed, create a more harmonized application of rules across the EU; better reflect recent technological and scientific advancements within the medical device sector; and ensure medical devices are safe and effective through tighter controls.

The EU medical device market: An overview

The 27 countries making up the European Union (EU) include over 500 million consumers. According to the European Commission, the medical device market generates EUR 100B in sales each year, and accounts for 30% of the world market for medical technologies. The sector consists of over 25,000 companies, 80% of which are small- to mid-sized enterprises.

What's changed?

The new rules consist of two regulations, one governing medical devices (MDR) and one governing in vitro diagnostic medical devices (IVDR). They also introduce:

- An EU database covering all medical devices (EUDAMED). The database provides a comprehensive overview of all products available on the EU market;
- A device identification system using a unique device identifier (UDI), aimed at improving device traceability; and
- An **implant card** for patients containing information about their medical device.

Medical device manufacturers (MDMs) already compliant with the MDD and AIMDD directives have a transition period before they have to comply with the new regulations. Those with valid directive certificates can place products on the market after the initial MDR application deadline and until May 26, 2024. Legacy devices under these directives don't have to meet UDI requirements, but MDMs will have to register them in the EUDAMED database.

Directive, regulation – what's the difference?

A **directive** requires EU countries to achieve a certain result but gives them the freedom to decide how they will do so. EU countries incorporate certain measures into their national laws in order to meet the directive's objectives. A **regulation** is a legal act that applies automatically and uniformly to all EU countries as soon as it is enacted.

[1] **Directive 98/79/EC of the European Parliament and of the Council** on in vitro Diagnostic Medical Devices

[2] **Council Directive 93/42/EEC** on Medical Devices (MDD)

[3] **Council Directive 90/385/EEC** on Active Implantable Medical Devices (AIMDD)

Postponed date of application

As a result of the COVID-19 pandemic and the impact it's had on markets across the world, the European Parliament and Council have agreed to postpone the EU MDR date of application from May 2020 to May 2021. The thinking behind this delay was that it would allow member states, and their healthcare sectors, to prioritize the fight against the virus pandemic. The IVDR date of application remains the same: May 26, 2022.

For many MDMs, this delay was a much-needed reprieve. In addition to being able to focus their efforts on pandemic-related research and activities, the delay also gives them an opportunity to take a much more considered approach to compliance. MDMs can use the time to examine their labeling, and create a long-term strategy, as opposed to implementing short-term quick fixes. In the next section, we'll look at how MDMs can use this extra time to make their labeling processes MDR-ready.

Medical Device Regulation timeline

- **Entry into force**
  May 25, 2017
- **Date of Application deadline**
  MDR:
  May 26, 2021;
  IVDR:
  May 26, 2022
- **EUDAMED launch**
  May 2022
- **Maximum validity of MDD certificates**
  May 27, 2024

What EU MDR means for your labeling

If you've had to comply with the previous EU medical device directives, you'll notice that the new regulations introduce quite a few significant changes which impact your labeling. For example, labels need to be in a human readable format, which you can supplement with machine readable information, such as RFID or bar codes. Labels must be legible, according to the user's technical knowledge, experience and training[4]. There are also specific requirements for sterile barrier labeling, absorbed materials and for warnings related to harmful substances. Medical device labels should indicate that the product is in fact a medical device, and use internationally recognized symbols, where appropriate. As something new, EU MDR introduces a harmonized standard for the Medical Device symbol, which you'll also need to implement on your labels. EU MDR also stipulates that the mandated label information be placed on the device itself (unless it is impractical or inappropriate to do so).

Meeting these requirements will most likely require a complete redesign of your existing labels, a task that will be particularly daunting if you're using legacy label design software or approaches, such as hard-coding label templates in SAPScript or using programs like Microsoft Word to design labels. Before we get into how you can make this redesign process easier and more efficient, let's take a closer look at one of the most significant changes from a labeling perspective: the UDI requirement.

Deep diving into UDI

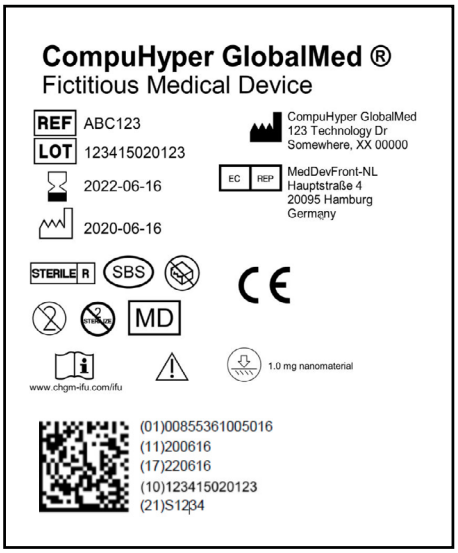
MDMs who have shipped product to the United States will be familiar with the UDI concept from the FDA UDI requirements. There are, however, key differences between the FDA and EU approach to UDI. One of the key elements of the EU MDR's version of the UDI requirement is the introduction of the Basic UDI-DI. The Basic UDI-DI identifies and connects devices with the same intended purpose, risk class and essential design and manufacturing characteristics. It's not a part of the packaging or labeling on the device, and it doesn't appear on any trade item. It's the main key in EUDAMED and relevant documentation and serves as the access key for device-related information entered in the database. MDMs have to assign a UDI and a Basic UDI-DI to all their medical devices and register this information in the EUDAMED database.

[4] Annex 23 1a

The UDI consists of two main parts:
the device identifier (DI) and production identifier (PI).

The **device identifier (DI)** is provided by an issuing agency (GS1, HIBCC, ICCBBA or IFA GmbH) and includes:

- Device version or model
- Device labeler
- Package quantity (unit of sale, multi-pack, etc.)
- You can only associate a DI with one Basic UDI-DI.



The **production identifier (PI)** is conditional and variable. If it's included on the device label, it includes the following:

- Lot/batch number
- Serial number
- Software identification
- Expiration date
- Manufacturing date (if the expiration date is not included)

Implementing UDI

For each medical device, you have to do the following:

- Assign a UDI and a Basic UDI-DI
- Register both UDI and Basic UDI-DI in the EUDAMED database
- Place the UDI carrier on the device label or packaging. If it's a reusable device, you have to place it on the device itself (direct marking). If your device is software, you have to assign the UDI at the software's system level.

Five steps to ensure UDI compliance

As we mentioned at the outset, the one-year delay gives you the opportunity to take a more measured, strategic approach to compliance. However, it's important to use the time wisely. In this section, we highlight five steps that will help you on the road to UDI compliance. We'll also talk about how to review your existing labeling processes and ensure you're using the best system and approach for your business, both now and in the future.

STEP 1	STEP 2	STEP 3	STEP 4	STEP 5
Set up the process.	Develop an internal process for UDI and EUDAMED registration requirements.	Submit your UDI data to EUDAMED.	Update your labels.	Go into production.

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A few points about Steps 1-3

Remember to look beyond the regulation itself and uncover the hidden costs and problems you might have in your existing workflow. Keep in mind that compliance exercises are about more than buying a tool or a system; they're about process improvement. And any process improvement exercise starts with people – identifying the stakeholders involved in the process and getting them all on the same page. The importance of this step cannot be underestimated. One of the primary reasons compliance projects go wrong is because the project managers failed to identify a stakeholder critical to the process. As you work with your stakeholders, it's important to clearly assign roles and responsibilities for each stage of the process. Try to answer the following questions:

- What role will IT play in the process?
- When will the quality and regulatory teams get involved?
- Who will be responsible for data updates and maintenance?
- What about security?
- What role will contract manufacturers, relabelers, repackagers and other external vendors play in the process?

And remember, instead of using existing processes and tweaking them to fit the EU MDR, find ways to improve them and then implement technology on top of that optimized process.

TIP: For more information about submitting UDI data to EUDAMED, visit ReedTech.com/UDI.

Step 4: Getting your labels in order

Simplify label design

The 'Updating your labels' step includes creating the new designs and verifying them. As you've seen in our brief discussion of the new labeling requirements, redesigning your labels to satisfy EU MDR will be quite a task. Think about how you can simplify label changes, not only in connection with the EU MDR changes, but also in anticipation of the countless requirements other countries are putting into place. When considering which type of labeling system would best suit your needs, try to address the following questions:

- How much time will IT staff spend updating labeling templates?
- Can I make it easier and less time-consuming for them by switching from hard-coded label templates to dynamic templates?
- Can I give staff access to a more intuitive label design software that will make it easier for them to update and maintain label templates?
- Can I automate mass label changes and approvals?
- As business are shifting to a more remote work environment, can I make labeling accessible to off-site staff?

TIP: By implementing a cloud-based labeling solution, you can ensure that any authorized person can design and change labels regardless of where they are.

Digitize your quality approval workflow

Rather than taking a manual approach to quality control, digitize quality assurance by incorporating review and approval workflows into your label management system. This will give you improved accuracy, transparency and efficiency. Your label management system also needs to enable you to lockdown UDI information to reduce the

likelihood of errors or unapproved changes. Also, think about how you will handle and approve mass label changes. Instead of manually creating hundreds or thousands of label designs for each SKU that then need to be approved, implement a labeling system that can automate mass label changes and approvals. In this way, the approved label template for each SKU is locked down or "frozen" with DI data and ready for production, where you can add PI data from the manufacturing execution system (MES), product lifecycle management (PLM) or enterprise resource planning (ERP) system.

LEARN MORE: Find out how NiceLabel's variant technology enables you to review and approve labels at the SKU level, without having to manually create multiple label variations.

Integrate labeling with DI and PI data

Think about where you will house your DI and PI data, and how you will integrate it with your labeling further down the line. Consider the advantages of integrating your labeling system with your cloud or on-premise business systems. You may house your DI data in an ERP system like Oracle or SAP, and your PI data in a product lifecycle management (PLM) system, a manufacturing execution system (MES) or a proprietary system. Regardless of where the data is stored, integrating these systems with labeling will provide you with a single source of truth for your label data. If your company has a Cloud-first strategy, or your business systems are Cloud-based, make sure you select a label management system that offers a Cloud option and supports Cloud-to-Cloud integration.

LEARN MORE: See how Label Cloud, NiceLabel's cloud labeling solution, handles Cloud-to-Cloud integration.

Integrating label printing with your ERP will also enable you to preview populated labels, directly within these business systems, prior to printing. This will afford your staff an extra opportunity for quality checks. And be sure your system provides you with a complete label print history in case of audits or other regulatory reporting.

5 Step 5: Moving into production

One of the critical tasks before going live is completing system validation. Whether you use an off-the-shelf solution or you've configured your labeling solution to your environment, you will need to validate it. Here it can help to use a validation tool that aligns with regulatory requirements, which can simplify compliance with industry standards and make it easier for you to maintain a validated, compliant labeling solution. Keep in mind that by standardizing on a single labeling platform with a digitized quality workflow, you only have to validate one system, as opposed to individually validating multiple, disconnected modules.

If you host your labeling solution in the cloud you also must consider how to handle periodic releases and updates. A multi-tenant cloud labeling solution will enforce a specific update schedule and validation activities will need to abide to it. With a single tenant cloud labeling solution, you have more control over when updates will happen so you can plan corresponding validation exercises. Finally, a privately hosted solution gives medical device manufacturers complete control over the release schedule however for security reasons the update procedure needs to be planned in advance.

TIP: Learn more about NiceLabel's Validation Acceleration Pack

Extending compliant labels to contract manufacturers

Once you've created an MDR-compliant labeling process, you want to ensure your labels stay compliant, no matter who prints them. Consider granting your suppliers and contract manufacturers remote access to your labeling system using Cloud technology. In this way, you can guarantee that your labels are accurate and compliant, because they are printed based on templates and data housed in your own systems. You control who has access to what, and you get a complete history of every label that's been printed, no matter if it's in-house or at a contract manufacturer. You can manage labeling centrally and reduce security risks without placing an additional burden on your IT resources. Taking a Cloud- based approach will also make it easier to onboard new suppliers, regardless of their IT infrastructure.

EU MDR: the opportunity

To recap, as with any regulation and the accompanying compliance exercise, MDR represents both opportunities and risks. MDMs everywhere are fully aware of the risks of non-compliance, yet not to be overlooked are the risks associated with a stopgap approach to compliance. You could end up with disconnected processes and manual workarounds, which, in the end, increase your time to market and decrease your competitiveness. To mitigate these risks, it's important to look at how you implement your MDR-compliant labeling processes, so that you end up with an efficient, streamlined approach to labeling. Which brings us to the opportunity. Turn EU MDR compliance into your competitive advantage by:

- Selecting a label designer that enables your staff to quickly design UDI-compliant labels;
- Digitizing your quality approval workflow to guarantee compliant labels;
- Making mass label changes easy by approving "frozen labels" that have a label variant for every SKU;
- Integrating labeling with DI and PI data from your business systems for a 'single source of truth';
- Making validation easier by implementing a single, standardized system with digital quality processes; and
- Extending compliant labeling to contract manufacturers and other business partners.

Let us help you seize the opportunity

For over a decade, NiceLabel has been working with the world's leading medical device companies to help them digitally transform their labeling and meet industry regulations. In fact, 38% of the medical device companies on the Fortune 2000 list use our technology. We know that labeling is a business-critical function in the medical device industry. Your labeling system needs to meet the unique regulatory requirements and market demands in every country where you do business. By implementing our label management system, either in the Cloud or on-premise, you can respond more quickly to new industry regulations, ensure accurate, consistent labels and get products to market faster. We work with you to ensure your system is configured and implemented according to best practices, and that it is validated according to medical device industry standards. We're here to turn compliance into your competitive advantage.

Contact our Medical Device Labeling Specialists

About NiceLabel

NiceLabel is a leading global developer of label design software and label management systems that help companies of all sizes improve the quality, speed and efficiency of their labeling, while reducing cost.

With the help of our label management systems, organizations are able to digitally transform their entire labeling process, from design to printing to label management. The result is a leaner, more agile operation that enables companies to respond more quickly to changing market conditions and requirements, get products to market faster and compete more effectively in the sectors where they do business.

Through its headquarters in the EU (Slovenia) and global offices in Germany, USA, Singapore and China, NiceLabel serves and supports its clients around the world with technology at the forefront of market demand.

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