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EU MDR and IVDR: Uncovering Hidden Cost Savings While Complying with Device Traceability and UDI Requirements

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Introduction

In 1987, when there were just 12 countries in the European Union (EU), the first Medical Devices Directive (MDD) was published. A year later, the In-vitro Diagnostics Directive (IVDD) was introduced to regulate in-vitro diagnostics (IVDs) in the European market. Today, with 28 countries and more than 600 million inhabitants, the requirements and pressures on the continent's medical sector are dramatically different, quite apart from the massive advances in technology and medical devices themselves.

The growth of the European Union has limited governability and contributed to a disharmony in the implementation of the MDD. While there has been some desire to address issues with the MDD, certain actions to improve the directive were halted by some member states that wanted to maintain their sovereign rights. Separately, differences in interpretation of the MDD led to inconsistencies between Competent Authorities. Since the initial MDD and IVDD, the EU has taken steps to update its rules.

- A 2007 directive clarified definitions of clinical data and member states agreed to create an essential European database, known as EUDAMED.
- In 2012, the European Commission proposed a new package of health measures designed to ensure a high level of health and safety protection for EU citizens, to promote free and fair trade of medical products and to account for technological and scientific progress. The first version of the Medical Device Regulation (MDR) and the In-vitro Diagnostics Directive (IVDD) were published by the European Commission.
- The text of the MDR and IVDR were adopted by the Council and Parliament in March and April 2017. This marked the last step in overhauling the regulations. The MDR and IVDR were published on May 5, 2017 in the Official Journal of the European Union and entered into force on May 25, 2017. The MDR regulation will apply on May 25, 2021, four years after its entry into force and the IVDR will apply on May 25, 2022, five years after its entry into force.

The new regulations have more legal weight than those they replace, with more stringent clinical data requirements, more need for data management and a more complex assessment procedure.

This white paper will outline the significant challenges medical device companies may have as they comply with these new regulations. It will also explore the device traceability portion of the MDR and IVDR and uncover lessons learned from the United States Food and Drug Administration (FDA) Unique Device Identification (UDI) regulation. Finally, it will provide a list of actionable steps that medical device manufacturers can take to ensure device traceability compliance, and how they can reduce operational costs along the way.

Companies that distribute products in the EU, or who aim to do so in future, need to ensure that they comply with MDR and IVDR ahead of their application.

The main reasons for the new regulations

The principle goals of the MDR and IVDR are to ensure the health and safety of EU patients and users, to establish a 'level playing field' across Europe in the trade of medical products, and to ensure that EU legislation covers the many technological and scientific advances of recent years.

In the years since the initial EU MDD in 1987, as the number of EU member states has grown, differences in interpretation and implementation of these directives have emerged between states which lead to different levels of patient and public health protection. Areas of concern include discrepancies between Notified Bodies (NBs), the development of hybrid technologies, and complex bureaucratic procedures for resolving disputes.

The MDR and IVDR will leverage advances in technology to improve transparency in the medical device market through standardized data and establish the European Database on Medical Devices (EUDAMED).

The MDR and IVDR establish an equivalent to the Unique Device Identifier (UDI) system developed by the FDA, with robust, transparent, predictable and sustainable regulations.

What are the main terms of the new regulations?

- Clinical data requirements will be more stringent
- Data management requirements will be extended
- Conformity assessment procedures will be more complex
- The European Commission will be responsible for overseeing EUDAMED and other databases
- Manufacturers will be required to submit documents summarizing the safety and clinical performance of their devices
- There will be a new risk classification system for diagnostic medical devices, in line with international standards
- UDI will be introduced to facilitate traceability of medical devices. Each will have a device identifier (DI) and production series, and batches will have a production identifier (PI). This will enable products to be traced through the supply chain from manufacturer to final user.

Labeling challenges companies will face as they prepare for the MDR

Many medical device manufacturers are working with labeling systems that are poorly suited to the demands of the MDR and IVDR. They may have legacy labeling systems dating back some years, or systems they have inherited as the result of a merger. These legacy systems lack the ability to facilitate extensive quality control and provide a full audit trail of labeling activity.

Some companies are using several different business systems to manage variable label data, such as Oracle, SAP or home-grown systems. To complicate matters, these systems often aren't integrated with the labeling system which increases the chances of redundant or inaccurate information on labels.

Some continue to employ manual labeling processes, keeping a physical catalogue of labels and employing teams of people to inspect and approve labels. With a high probability of human error, these companies are vulnerable to mislabeling.

It is important to have a full record of label printing activity. When companies employ decentralized or manual labeling processes, it is almost impossible to capture print history.

Some companies have different label designs and processes for different product families. This leads to inconsistency and a situation where nobody in the business has full control of the final label output.

There are various consequences for medical device manufacturers as a result of these issues:

- Errors in labeling can lead to products being quarantined, affecting the production and distribution process
- Products may have to be recalled, causing financial damage and impacting the business' reputation
- Non-compliance could result in financial penalties or other sanctions

In response, medical device manufacturers selling in Europe need to consider how best to adapt their labeling systems to comply with the new regulations.

Requirements for data collection and device traceability

The main data collection and device traceability requirements of the directives will include:

- Medical device manufacturers must establish risk management systems, including a new risk classification system for diagnostic medical devices, and quality management systems.
- They will also have to observe stricter rules for conducting clinical investigations and reporting the findings.
- Manufacturers will also be obliged to collect data about the real life use of their devices.
- Unique Device Identification (UDI) codes must be included on medical device labels.
- The EUDAMED database will provide comprehensive information on products available in the EU market.

What lessons can be learned from the United States' experience with UDI?

As in the U.S., the regulations in Europe are largely based on the International Medical Device Regulators Forum (IMDRF), and there are many similarities between the regulations in the two markets. Medical device manufacturers who sell products in Europe can benefit from some of the lessons learned in the U.S. implementation of UDI.

The rolling UDI program instigated by the FDA, began in September of 2014, and obliged medical device manufacturers selling products in the United States to submit UDI details to a central database, in order to improve safety, record keeping and tracking of devices.

This process was lengthy and expensive for many companies. It typically involved choosing an issuing agency to work with, obtaining identification codes, adopting new labeling formats and technologies and formulating a strategy for GUDID (Global Unique Device Identifier Database) submission.

There were many hurdles for companies' labeling processes in GUDID submission, including:

- Choice of technology to make GUDID submissions, such as software as a service (SaaS).
- Whether to outsource the submission process
- Setting up labeling systems to comply with UDI requirements and GUDID submission criteria
- Deciding whether to set up a centralized label management solution

The further ahead companies began to prepare for GUDID submission, the more effectively they were able to comply with its requirements. Those companies who left decisions until the last minute found that they suffered from delays and inconvenience, and benefited less from the new labeling infrastructure.

Those who adopted compliant technology ahead of time were also able to consider the wider implications of a modernized labeling system, such as being prepared for future regulations and with those outside the United States (including Europe).

Most importantly, companies who adopted a modern labeling solution reduced any risk of product recall due to lack of compliance.

Checklist of actionable steps to ensure compliance in labeling

To ensure device traceability compliance with the MDR and IVDR, medical device manufacturers should take the following steps:

- **Enable business users to create UDI compliant labels**
  Allowing business users to design, review, approve and control label data will streamline compliance, and eliminate the need for costly IT resources to assist in label design. Business users will be able to easily add the UDI-DI specific to the model and UDI-PI which includes lot number, serial number, software identification and manufacturing and/or expiration date.
- **Secure and control access to data and resources for labeling and template files**
  Administrators should use role-based access control (RBAC) to regulate access to documents and resources and ensure that users only have access to the specific software features (e.g. label design, manual printing) and documents (label templates) that they need. By creating specific user roles and issuing unique logins for each user, label management systems provide an added layer of transparency throughout the label production process.

- **Create a comprehensive and robust architecture for all labeling needs**
  Undertaking a compliance effort presents a unique opportunity to examine existing labeling systems and processes. While the status quo can likely satisfy the UDI requirements of the MDR and IVDR at a basic level, it may pose challenges as the business grows and labeling is extended to new sites. A modern, web-based label management system enables business wide access, and faster label design and approval workflows without needing to install software on local workstations.
- **Automate your labeling process to remove human error and increase speed**
  Using a label management system reduces the likelihood of human error due to manual data entry. Label templates can be controlled so that print operators don't need to make edits. Label management systems also enable users to preview any changes made prior to printing, providing another opportunity for quality checks.
- **Adopt a labeling system with versioning and workflow capacity to control the label lifecycle**
  Implementing a label management system allows users to update labels from one central location. Once changes are implemented in the document management system, they are automatically made available to all manufacturing sites. Responding to new regulatory requirements is easy, as the adjustments only have to be made in one place. Labeling new devices or incorporating products acquired as the result of a merger or acquisition can be done quickly and easily. A full print history lets users know exactly what was printed in the event of an audit.
- **Recognize the level of collaboration that may be necessary across company divisions**
  With sites spread across the globe, international medical device companies have the challenge of ensuring labeling operations are consistent in different geographies. Any company shipping devices to the EU must comply with MDR and/or IVDR labeling requirements, heightening the need for collaboration and consistency across divisions. This factor is commonly underestimated, as companies approach regulatory deadlines. A label management system will centralize labeling processes and provide an oversight mechanism to ensure uniform global labeling.
- **Look for a labeling solution that can integrate easily with existing IT systems**
  A label management system with streamlined integration to business systems makes it easier to identify potential errors before devices are shipped. Regardless of whether the production identifier (PI) data needed for compliant device labeling is housed in an ERP system like Oracle or SAP , a warehouse management system (WMS), or a proprietary system, integrating these systems with labeling provides a single source of truth for label data.

Reducing costs as part of an MDR/IVDR compliance initiative

In many cases, medical device manufacturers that implement a modern label management system as part of their compliance effort reduce labeling operational costs, ship products faster and sell more.

Direct cost savings opportunities	Indirect (hidden) cost savings opportunities	Profit & growth opportunities
Faster label design	Greater accuracy	Supply chain efficiency
Streamlined software integration	Increased reliability	Reduced inventory costs
Process integration	Improved standardization	Get products to market faster
Rapid deployment	Better transparency	Easily scale the business
Faster printing		Win and retain more customers

To identify the potential costs savings for your organization, consider the following questions:

- How many people/shifts are involved in the design and print process?
- Can your business users create or change labels?
- How long does it take for you to process label change requests?
- How many templates or label variations do you have to create and manage?
- How much do you rely on your IT department for support and maintenance?
- Have you ever had any fines or penalties for mislabeling or lack of compliance?
- Has manual data entry resulted in label errors?
- What is the cost associated with reworking labels that have errors?
- Have you ever had to quarantine products or have you lost business due to mislabeling?
- What do shipping delays or production shut downs cost your business?

Conclusion

The challenges of complying with the European MDR and IVDR legislation should not be underestimated. This is an increasingly complex field, where the penalties for non-compliance – both financial and loss of reputation – are increasing, along with the risk of commercial disruption.

At the same time, the advantages of adopting a modern, robust and secure labeling technology are numerous. Your company will save time and resources while gaining increased transparency, traceability, accuracy and quality control; quickly repaying the initial investment and helping your business to comply with the MDR, IVDR and potentially other regulatory regimes.

You should consider a labeling system with versioning and workflow capabilities, along with label version comparison, to maximize quality control and consolidation of existing label templates. Validation is another highly valuable facility.

While gaining compliance with new regulations can appear burdensome, consider it an opportunity to make a valuable and timely upgrade to your labeling technology.

About Loftware NiceLabel

Loftware NiceLabel is the leading developer of label management software solutions for the life sciences industry. Our solutions enable medical device manufacturers to comply with device identification and traceability labeling re-quirements, eliminate errors and quickly respond to label change requests, all without costly development cycles. Through its headquarters in Europe and global offices in Germany, the USA, Singapore and China, NiceLabel provides its clients with the best technology that delivers ROI that exceeds expectations.

We Are KEY FOR INDUSTRY

KFI – Key For Industry
Via delle Scienze, 21
20082 Binasco (Milan) Italy
Ph. +39 02 905731
info@kfi.it

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