Keeping track of traceability – preparing for the EU medical device regulation

Introduction

The term 'medical device' is broad and covers a wide range of items. It is referred to most commonly as an apparatus or a piece of equipment that is used to treat or diagnose a condition that comes into direct contact with the patient. Whether it is a simple pair of contact lenses or a more sophisticated device such as a pacemaker, the frequency with which we encounter medical devices in our day-to-day lives is surprisingly high and the key role they play in our well-being remains undeniable.

It is because of this role that regulations surrounding medical devices tend to be placed under more stringent scrutiny.

Under the FDA (Food & Drug Administration) rule in the USA, manufacturers have been required to implement UDI (Unique Device Identification) on all medical product packaging since September 2014. Following this and in light of the recently adopted EU Medical Device Regulation, European manufacturers of medical devices will face even tougher regulations to ensure their products are safe to use under new EU laws that are scheduled to come into effect from May 26th 2020 onwards.

The new regulation will also see the introduction of a new Unique Device Identification system. This means that for traceability purposes, medical devices sold in the 28 member states of the EU as well as Iceland, Liechtenstein, Norway and Switzerland will need to include a UDI code. The details of the UDI will need to be recorded in an EU database known as EUDAMED. With this legislation coming into effect, manufacturers now have a responsibility to invest in a coding solution that allows them to apply traceability codes onto products as well as packaging.

Breakdown of medical product classes

- **Class III:** implantable pacemakers, pulse generators, HIV diagnostic tests, automated external defibrillators, endosseous implants and contact lenses for extended wear.
- **Class II a/b:** acupuncture needles, daily wear contact lenses, powered wheelchairs, infusion pumps, surgical drapes and implantable radiofrequency transponder systems for patient identification and health information.
- **Class I:** elastic bandages, examination gloves, and hand-held surgical instruments.

For the classification of all medical devices refer to Annex VIII and Annex XVI included within the EU MDR.

As a global leader of high quality coding and marking solutions, Domino Printing Sciences is well placed to help these manufacturers meet the emerging requirements. The following white paper aims to identify the coding applications encountered most often in the medical industry and highlight the ways in which different coding and marking technologies are equipped to tackle them.

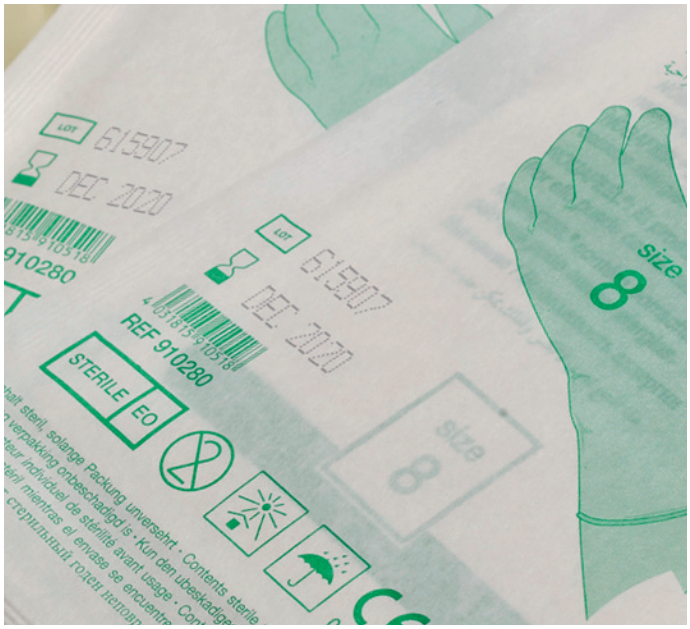
Industry background

Based on manufacturer prices, the European medical technology market is worth €110 billion and is estimated to make up 28% of the world market, making it the second largest in this sector after the USA. There are approximately 25,000 medical technology companies in Europe, with over 575,000 registered employees. Market research reveals that small and medium-sized companies (SME's) make up almost 95% of the EU industry and that the majority of them employ less than 50 people per company.

European market overview

- Western Europe represents approximately 28% of the global medical device market.
- In Europe, Germany represents 30% of the market, followed by France (15%) and the UK (13%).
- In Western Europe, the current compounded annual growth rate for the medical sector is 3.7%; in Northern Europe a 5.1% compounded annual growth rate is forecast in the next five years.

Source: MedTech Europe and IBISWorld



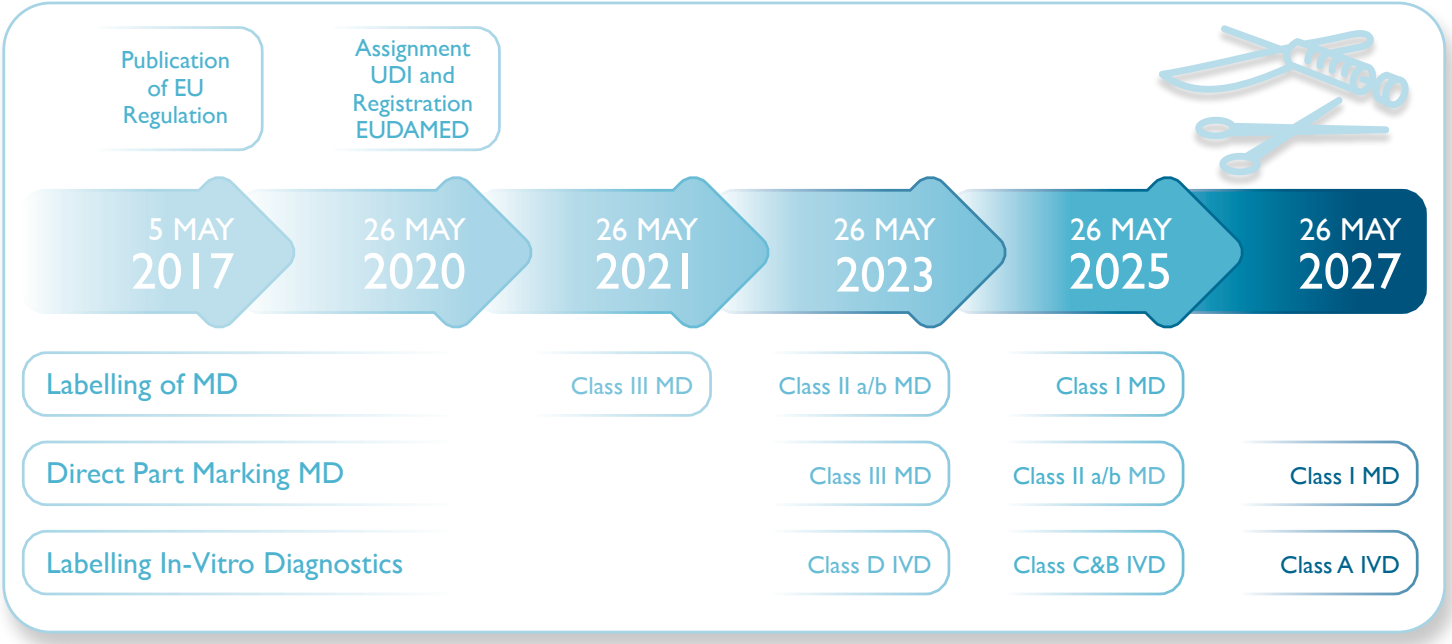
The current rules relating to the safety and performance of medical devices in the EU date back to the 1990s. However, the substantial scientific and technological advances in the medical sector that have taken place since their implementation have prompted the EU Commission to update the rules. The view is to improve the safety and performance of medical devices for EU citizens, while also creating the conditions to effectively modernise the sector and further consolidate the European Union's role as a global leader.

How does the EU regulation affect coding and marking?

With the new EU regulations coming into play, medical device manufacturers have a legal requirement to ensure that a UDI code is assigned and registered in EUDAMED for every single item they produce by the May 2020 deadline. The May 2021 deadline marks the beginning of mandatory UDI coding onto medical devices starting with Class III devices.

Failure to comply with the legislation will have repercussions. Manufacturers will no longer be able to supply their products to every EU member state. Fee payers and healthcare providers, will not accept devices without UDI codes that are up to the required standard.

As a result, manufacturers now face a responsibility to familiarise themselves with the exact requirements of the legislation and ensure they have a coding and marking solution in place that can meet their needs, ahead of the stipulated deadline. However, to understand these requirements, a comprehensive audit and evaluation of the technologies available on the market is needed.



Timeline of UDI registration and coding of medical devices.

The role of coding and marking in the medical sector

The technology to assign, apply and verify identification codes to a wide range of products is an invaluable asset. The benefits are varied and apply to numerous industries such as the medical sector, where UDI is the accepted method for identifying and tracing medical devices throughout their lifecycles, from production through to distribution and finally to consumer use.

The implementation of product codes onto medical devices results in more efficient recall procedures, the reduction of medical errors, as well as increased inventory visibility and supply chain security. The unique codes applied to each item during the manufacturing stages will provide the supply chain management system with key information, such as what the product is, where and when it was produced, its current location and how it got there. In the event a recall is necessary due to a product being faulty, the code is crucial to unlocking the so-called 'chain of custody', allowing the item in question to be traced back to its origin.

As is the case with other industries, counterfeit products can harm a medical brand in many ways, from affecting business revenues, to destroying consumers' faith in the brand through poor-quality imitations. More importantly, counterfeit products can endanger consumers' health. Illicit trade can be even more detrimental, as it goes beyond simple counterfeiting to encompass equally damaging activities such as product diversion, where perfectly genuine products are deflected from intended channels into ones unauthorised by the manufacturer. With this in mind, item-level identification proves to be effective in helping to distinguish legitimate products from the counterfeit ones, while also helping governments to stem the erosion of revenues and jobs caused by illicit trade.

Coding and marking technologies for the medical sector

Depending on the medical device and the coding surfaces involved, there are several different technologies that can be deployed for the delivery of UDIs in this sector.

Direct Part Marking

The most prominent technology for Direct Part Marking (DPM) on to medical devices is laser. While DPM is more commonly known as an industrial manufacturing application, it is most appropriate for medical device identification.

The presence of reprocessing devices throughout the supply chain can cause product items to be separated from their original packaging, which is why a permanent mark needs to be applied to the medical device. This way, a UDI code is readily available through the device distribution and use, even in the absence of packaging or labels. Medical devices such as pacemakers or surgical instruments are the kind of products that would require a permanent mark, as the UDI is designed to last as long as the device itself.

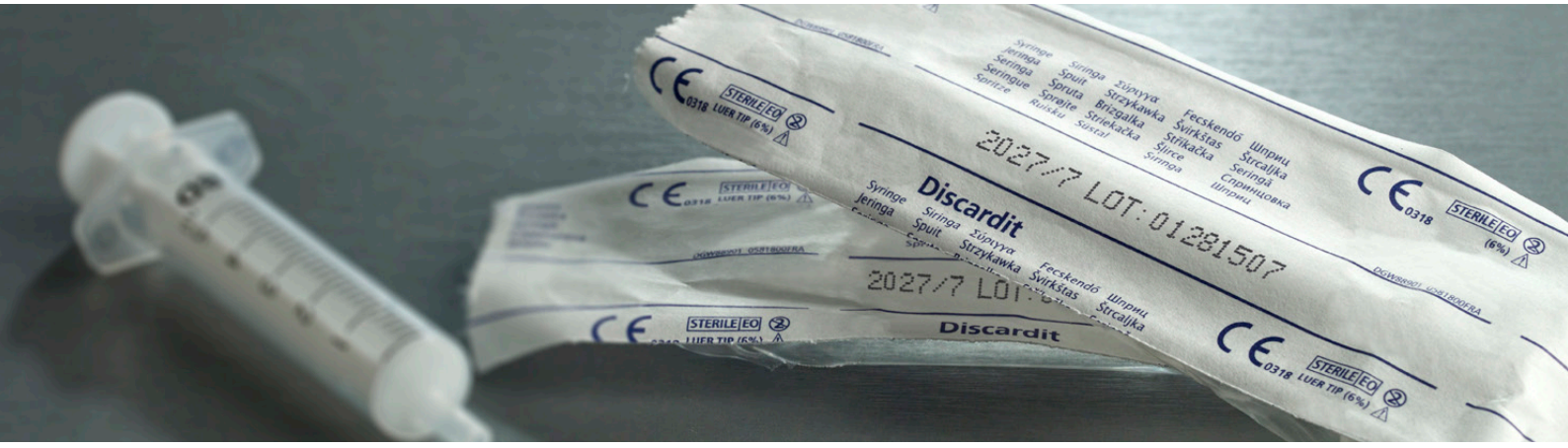
With code durability being the key priority, a fibre laser marker is the preferred solution provided the required contrast can be achieved. A solid-state laser system can permanently mark a variety of materials with the utmost precision, producing unlimited lines of texts, graphics or even 2D data matrix codes, resulting in crisp, sharp codes that will not deteriorate over time.

Primary packaging

In contrast to DPM, a variety of coding and marking technologies as well as laser can be used for applying UDI codes onto primary packaging. These technologies include Thermal Ink Jet (TIJ), Thermal Transfer Overprinting (TTO) and Print & Apply Labelling Machinery (PALM).

TTO is the preferred choice for coding onto flexible, web based packaging materials. These materials and packaging applications include flexible laminated films to create pouches, sachets and bags or to lid rigid trays and apply labels to the surface of other primary packs as well as coding directly onto speciality flexible materials, such as medical paper or Tyvek®.

TTO systems have the capability to print high resolution (300 DPI) human and machine readable codes to satisfy the UDI requirement and can also print graphics, logos and other variable text fields over large areas. This additional functionality can be used to decorate and customise packaging according to the unique content and gives the medical device manufacturer the future option of saving operating costs. This is done by reducing the number of packaging material Stock Keeping Units (SKUs) and reducing the downtime incurred by changing the packaging SKU during packaging job change-overs.



Specialised for printing high resolution codes at high speed, TIJ proves to be an ideal solution for all cartons and certain foils. These systems use solvent- and water-based inks to print complex and durable codes at a fast repeat rate, while still delivering the required legibility to meet the regulations for UDI coding. The ability to easily integrate a TIJ print head into multilane applications also make this system suitable for wider web coding applications. Employing multiple print heads to deliver individual codes across the substrate's surface from a single controller gives significant cost and productivity benefits.

Secondary and tertiary packaging

Where larger label information needs to be printed and applied onto cases, or a label is the only option due to the substrate or the shape of a product, PALM proves to be an effective alternative to TIJ and TTO. PALM can also be deployed for secondary and tertiary packaging applications. As well as the other technologies, PALM enables high resolution application of the required UDI and GS1 codes (used to to encode information such as product numbers, serial numbers and batch numbers) and offers multiple applicator options which includes corner wrapping of cases.

Conclusion

With the deadline now set in place to comply with the mandatory requirements of the EU regulations relating to medical devices, manufacturers have been given a timeframe to ensure they have all the affected areas of their business covered, including product identification.

As outlined throughout this report, there are multiple aspects to take into consideration in order to select the coding and marking system that is best suited for one's business, such as substrates and materials, production volume, data management, etc. More importantly, manufacturers need to manage their timeframes as effectively as possible and act now. Sufficient time needs to be allowed to test solutions and potentially make the necessary adjustments to manage the new coding requirements.

By taking action ahead of the deadline and partnering with a reliable supplier and partner that can provide the guidance and industry knowledge required, compliance can be successfully achieved.