European Medical Device Regulation (EU MDR) New requirements effective May 2021

Summary of changes

BD

A **new industry change** is about to take effect to ensure higher levels of safety and quality in the European medical device market.

In 2017, the new **EU Medical Device Regulation (EU MDR)** was approved to replace the existing Medical Devices Directive (MDD), granting all medical device manufacturers an initial three-year, now four-year, transition period to implement the changes.

As your medical device manufacturer, BD has taken measures to remain compliant with these upcoming changes for you to maintain seamless access in the European market.

A proactive approach and early preparation have helped BD to uphold the quality and supply to market you expect from our company.

Here is a brief summary of the new EU MDR.

FAQs

What is EU MDR?

The European Medical Device Regulation (EU MDR) will replace the EU's current Medical Device Directive (MDD) to ensure high standards of quality and safety for medical devices being produced or supplied in Europe.

What is the main difference between the two?

The new regulation replaces the current directive. Directive must be transposed into each member states laws and therefore allow for slightly different interpretation by each member state. As the EU MDR is a regulation, it must be applied across all countries and allows for no variety in interpretation by individual member states.

When did the new regulation take effect?

May 2021

How will this impact the medical device manufacturers?

All medical device manufacturers will need to recertify their product portfolio no later than May 2024, or before the expiry date of the current MDD CE certificate. This is the requirement of the regulation in order for the CE mark to be applied and to continue selling in the EU.

What products are affected?

All current medical devices, CE marked to the MDD, as well as any future products that will be launched in the EU are impacted by this change.

How will this change benefit me?

The new regulation contains more details on product, clinical, safety and quality requirements and related control in regards to post-market surveillance activities aiming to improve the safety of Medical Devices for patient.

How will I know the difference between current and future products?

With BD, the transfer from the current directive to the EU MDR should be seamless, although you will recognise some labelling changes as additional information will be required.

Do I need to do anything?

The impact of the new Medical Devices Regulation will have limited impact on hospitals and patients. However, their critical involvement will be required for clinical investigation, patient implant cards, patient information leaflets, post-market surveillance activities and product traceability.

What about my current product?

Although the new regulation went into effect on May 26, 2021, products manufactured under the current directive and products manufactured under the new regulation may coexist in the market and may be put into service and available until May 2025. MDD compliant products will not be marketable after May 2025. Products with expiry date and delivered to your hospital before May 2025 can still be used until their expiry date.

Are you going to phase out products?

The EU MDR contains significant regulatory changes that affect the entire medical device industry. We are conscious that the implementation of regulatory changes with the wide-reaching effects of the EU MDR presents a risk of creating logistical challenges. Phasing out products is a normal part of the life cycle of any product; if product phase-outs occur, we will work with our customers as we already do to ensure patient needs continue to be met.

Does the new regulation mean that products that are currently sold with a CE mark will not be legal?

No, we are currently in the transition period between the current directive and the new regulation. It means that MDD compliant medical device and EU MDR compliant medical device products can currently coexist in the market. Since May 26, 2021, only class I EU MDR compliant medical device can be legally placed on the market. However, class I MDD compliant medical devices can still be put into service until May 26, 2025. Class I medical device up-classified as per EU MDR and higher classified medical devices can continue to be legally placed on the market, until their existing MDD CE certificate expires or May 26, 2024, whichever comes first. They also can be put into service until May 26, 2025. These transition requirements are clearly defined in the EU MDR, in particular in article 120.

Are you going to recall products because of the EU MDR?

The new regulation does not mean that devices that were placed on the market under the MDD rules should be recalled from the market. We will continue to comply with our regulatory obligations concerning product post-market surveillance.

Is the EU MDR going to be applicable in the UK after Brexit?

We are of course aware that the United Kingdom left the European Union on January 31, 2020. The UK continued to recognise EU requirements until December 31, 2020, which was the end of the transition period for Brexit. After that date, the UK moved to self-regulation of medical devices, and implemented the Medicines & Medical Devices Act, 2021. The UK will allow medical devices that are CE marked to be placed on the market until July 1, 2023. After this date, products will have to comply with requirements which will hopefully be published later in 2022. BD is monitoring this situation as it continues to evolve.

What are the main changes?

EU MDR at a glance

More in-depth evidence

Additional clinical evidence and technical documentation will be required to support safety and quality claims.

Implementation of Unique Device Identification (UDI)

UDI consists of a series of numeric or alphanumeric characters that allows unambiguous identification of specific devices on the market. The unique identifier labelling shall facilitate the traceability of each device and enhance patient's safety. Like other countries jurisdiction, such as the US, the EU will now require unique identifiers on the device labelling to help track devices from manufacturing through distribution to patient use.

Increased post-market surveillance

This is achieved by device manufacturers including development of post-market follow-up plans. These plans include performance and clinical evaluations throughout the life of the product and reconfirm the benefits of the device outweigh the risks.

Increased oversight

Both notified bodies and medical devices manufacturers will be subject to more oversight by European competent authorities.

No "Grandfathering"

Each medical device will be required to be recertified to meet the requirements of the EU MDR.

EU MDR at a glance (cont.)

Labelling and International Organization for Standardization (ISO) symbols

The Medical Devices Regulation has new requirements that ask for various kinds of information to be indicated on all labels of medical devices including top web, shelf carton, case carton and case labels. Below are examples of new symbols:

Medical device indicator

MD

The words “exclusively for clinical investigation” will also be added when needed.

Contains hazardous substances

Indicates a medical device that contains substances that can be carcinogenic, mutagenic, reprotoxic (CMR) or substances with endocrine disrupting properties.

Contains human blood or plasma derivatives

Contains a medicinal substance

Single patient - multiple use

Unique Device Identification (UDI) carrier

Allows unambiguous identification of each specific device on the market.

Sterile barrier system

An indication permitting the sterile packaging to be recognised as such

Date of manufacture

Required to add the month and year of manufacture regardless if the product has an expiry date.

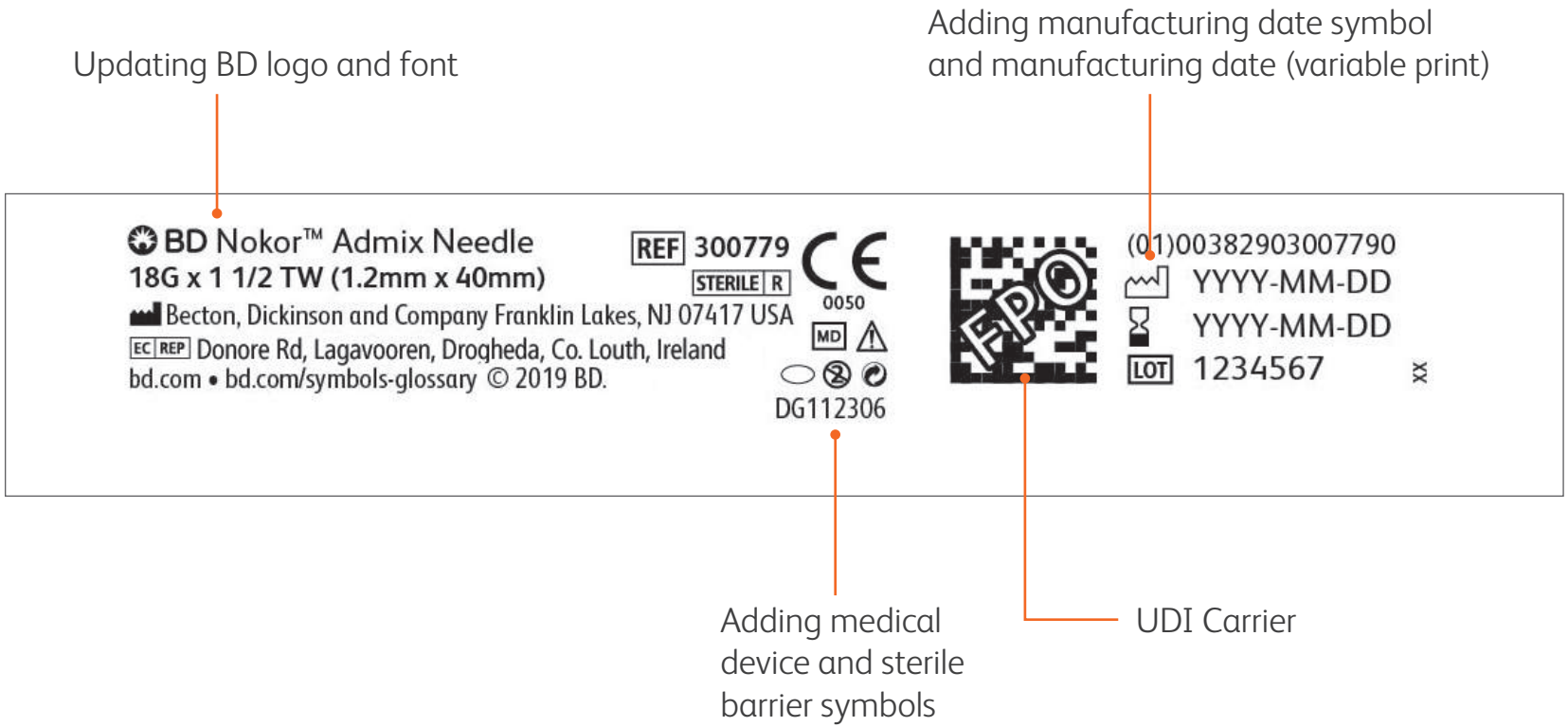
Consult instructions for use (IFU)

Available electronically if applicable.

EU MDR at a glance (cont.)

Revised top web example

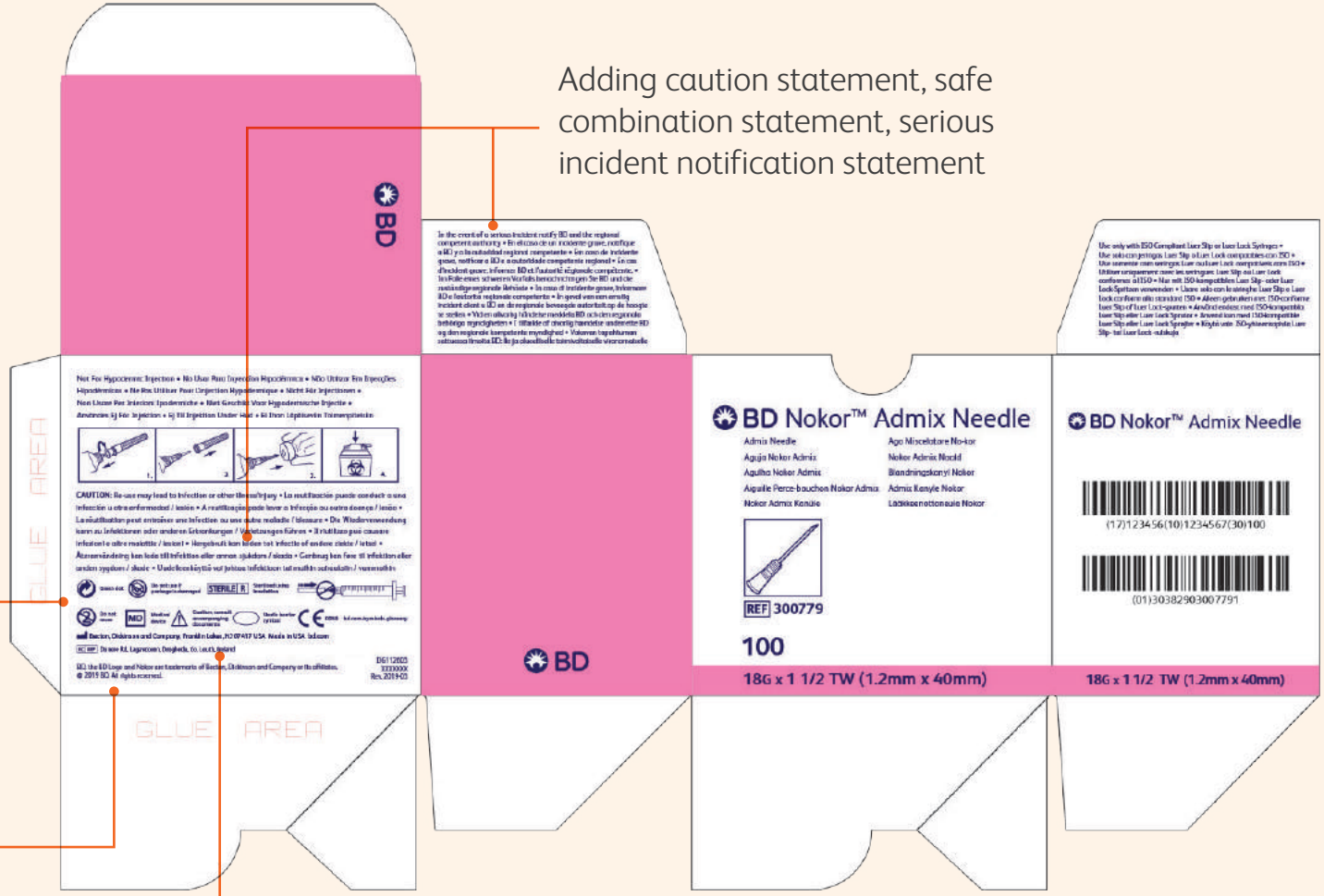
Revised top web example shows both EU MDR required revisions and internal revisions



EU MDR at a glance (cont.)

Revised shelf carton example

Revised shelf carton example shows both EU MDR required revisions and internal revisions

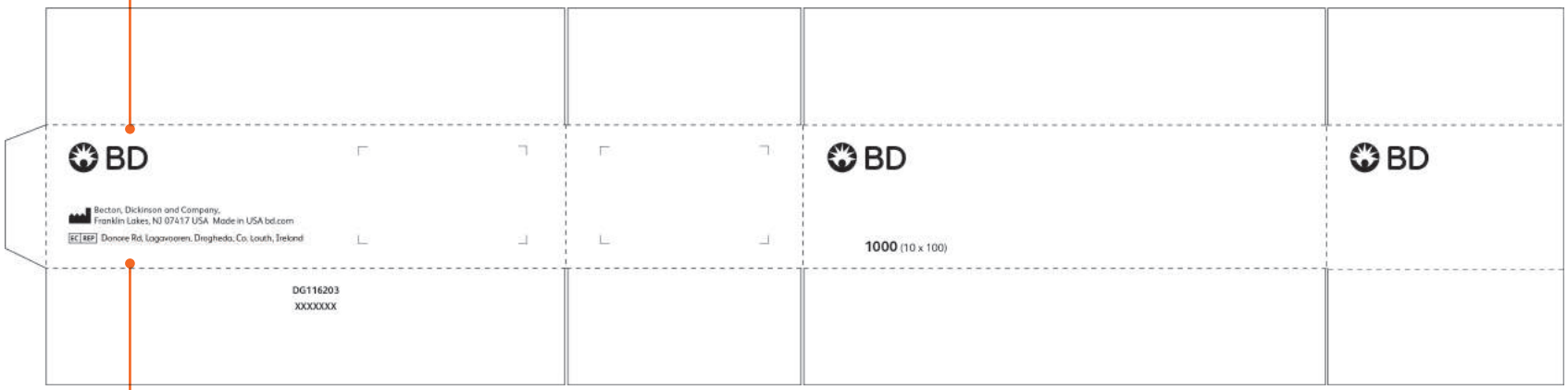


EU MDR at a glance (cont.)

Revised case carton example

Revised case carton example shows both EU MDR required revisions and internal revisions

Updating BD logo and font



Update EC-Representative address and adding symbol

EU MDR at a glance (cont.)

Revised case label example

Revised case label example shows both EU MDR required revisions and internal revisions

Adding quantity information

Add medical device and caution symbols

Adding copyright year, trademark byline, website and symbols glossary

Updating expiry date format to YYYY-MM-DD

Where can I learn more about EU MDR?

For more information, visit **bd.com.**

For more general information about EU MDR, visit:

https://ec.europa.eu/health/publications/factsheet-healthcare-professionals-and-healthcare-institutions_en

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