European Medical Devices Regulation (EU MDR) Requirements effective May 2021

Summary of changes
Updated following 2023 EU MDR amendment

BD

An **industry change** is taking effect to ensure higher levels of safety and quality in the European medical devices market.

In 2017, the **EU Medical Devices Regulation (EU MDR)** was approved to replace the existing Medical Devices Directive (MDD). Regulation (EU) 2023/607 has updated the transition period until the end of December 2027 for class III and class IIb implantable devices, except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors. For other legacy class IIb implantable devices not covered above, and class IIa, Is, Im, Ir, and I devices, the transition period has been updated until the end of December 2028.

The application of the extended transition period is subject to several cumulative conditions.

As your medical device manufacturer, BD has taken measures to remain compliant with these 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 updated MDR following Regulation (EU) 2023/607 amendment.

FAQs

What is EU MDR?

The European Medical Devices Regulation (EU MDR) will replace the EU's Medical Devices 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 regulation replaces the directives. Directives must be transposed into each member state's 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 regulation take effect?

May 2021

How will this impact the medical devices manufacturers?

All medical devices manufacturers will need to recertify their product portfolio to maintain the CE mark and continue selling in the EU.

What products are affected?

All 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 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 you notice the difference between MDD and EU MDR products?

With BD, the transfer from MDD to 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 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 regulation has been effective since May 26, 2021, products manufactured under the MDD directive and products manufactured under the EU MDR regulation may coexist in the market until end of December 2027 or end of December 2028, according to devices classes. Devices placed on the market before the end of the transition can be made further available on the market without any time restriction.

Are you going to phase out products?

The EU MDR contains significant regulatory changes that affect the entire medical devices industry. We are conscious that the implementation of regulatory changes with the wide-reaching effects of the EU MDR may present 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 regulation mean that products that are currently sold with a CE mark will not be legal?

No, we are in the transition period between the directive and the regulation. It means that MDD compliant medical devices and EU MDR compliant medical devices products can coexist in the market. Since May 26, 2021, only class I EU MDR compliant medical devices can be legally placed on the market. Class I medical devices up-classified as per EU MDR and higher classified medical devices can continue to be legally placed on the market, until end of December 2027 or December 2028, according to devices classes. These transition requirements are clearly defined in the EU MDR, in particular in article 120 and in Regulation (EU) 2023/607.

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

The 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?

Following the withdrawal of the United Kingdom (UK), comprising, England, Northern Ireland, Scotland and Wales, from the European Union (EU), referred to as 'Brexit', the regulatory requirements for products being placed on the market in Great Britain (GB) (comprising England, Scotland and Wales) is changing.

In April 2023, the UK government put in place a legislation (The Medical Devices (Amendment) (Great Britain) Regulations 2023 (SI 2023 No 627) which came into force from 30th June 2023 that amends the Medical Devices Regulations 2002 (SI 2002 No 618) (UK MDR) to extend the acceptance of CE marked medical devices on the Great Britain (GB) market.

UK will accept MDD or EU MDR certificates until 31 December 2027 for class III and IIb implantable devices, until 30 June 2028 for class IIb (other), class IIa, class Is and class Im, and EU MDR certificates until 30 June 2030.

After the applicable transition period provided by SI 2023/627, medical devices being placed on the GB market will need to meet the requirements of the applicable UK Medical Devices Regulations and bear the UKCA mark.

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 devices 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 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 symbols:

Medical device indicator

Indicates the item is a medical device. The words "exclusively for clinical investigation" will 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

Indicates a medical device that contains or incorporates human blood or plasma derivatives.

Contains a medicinal substance

Indicates a medical device that contains or incorporates a medicinal substance

Single patient - multiple use

Indicates a medical device that may be used multiple times on a single patient

Unique Device Identification (UDI) carrier

Allows unambiguous identification of each specific device on the market.

Sterile barrier system

Indicates a single sterile barrier system, allowing the sterile packaging to be recognised as such.

Date of manufacture

Indicates the date when the medical device was manufactured. Required to add the month and year of manufacture regardless if the product has an expiry date.

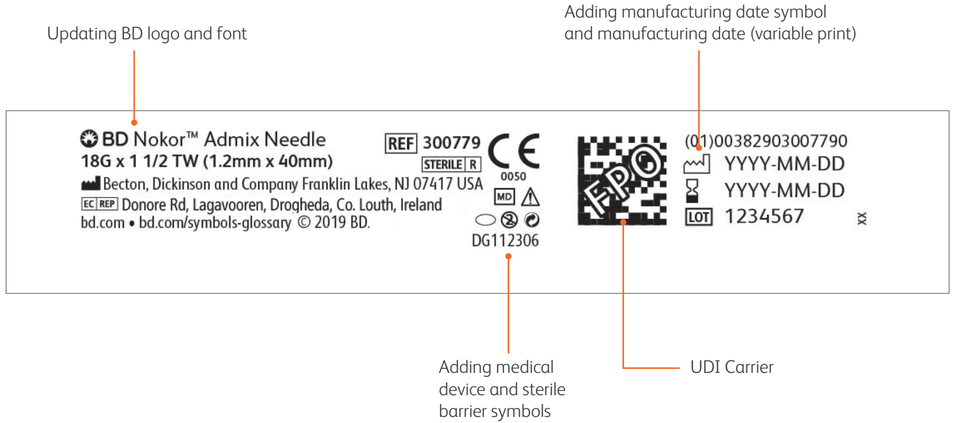
Consult instructions for use (IFU)

Indicates the need for the user to consult electronic instructions for use. Available electronically if applicable.

EU MDR at a glance (cont.)

Revised top web example

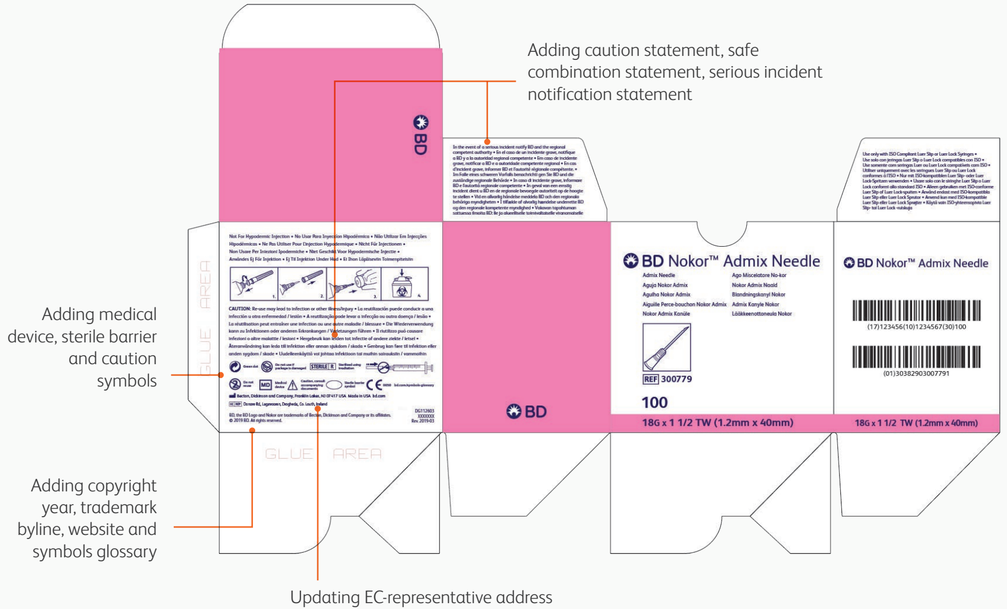
Revised top web example shows both EU MDR required revisions and internal revisions



EU MDR at a glance (cont.)

Revised shelf carton example

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



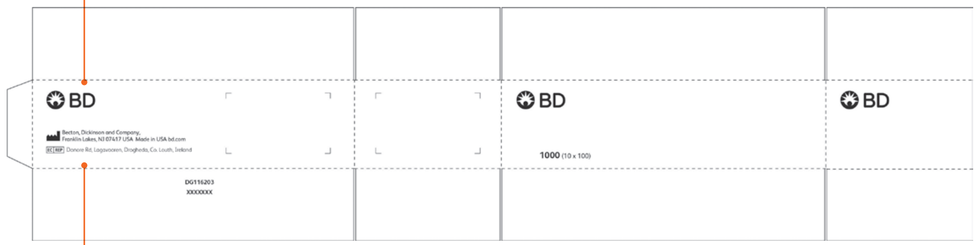
What are the main changes?

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



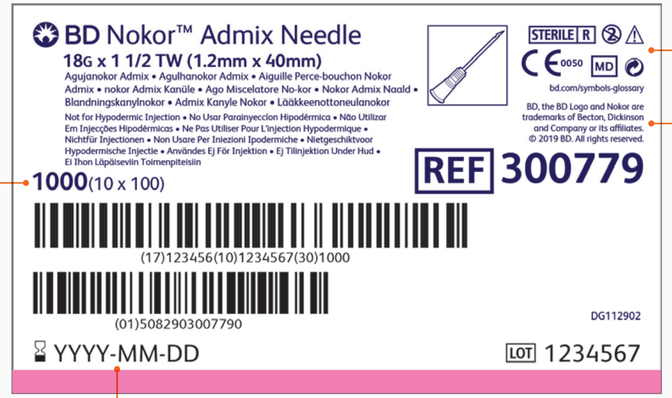
Update EC-Representative address and adding symbol

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

What are the main changes?

Where can I learn more about EU MDR?

For more information, visit **https://www.bd.com/en-eu/company/mdr-ivdr-update**

For more general information about EU MDR, visit:
https://health.ec.europa.eu/system/files/2023-07/mdr_proposal_extension-q-n-a.pdf

BD Switzerland Sàrl, Terre Bonne Park – A4 Route de Crassier 17, 1262 Eysins, Switzerland

bd.com