You & EU MDR

What You Need to Know

The EU Medical Device Regulation (EU MDR) is the biggest change of its kind in the medical device industry in recent history and **directly impacts every healthcare professional (HCP) and patient** working and living in the EU.

So, what does it mean for you?

This guide explains some of the changes and how Johnson & Johnson MedTech (JJMT) is supporting individuals, communities, and professionals to care in new ways.

What is EU MDR?

EU MDR is a mandatory regulation change that will govern how medical devices manufactured globally (by companies like JJMT) are sold in the EU and other markets that leverage the CE Mark.

Caring About EU MDR

As the world's largest healthcare company, we help shape what health and wellbeing means in everyday lives. JJMT has always followed the highest standards and supports new rules which continue to raise the bar for patient safety. Ensuring access to quality products for patients is at the heart of our values.

"We've been caring for people for more than 135 years and work tirelessly to continually redefine the future of patient care. We're privileged to have a presence in almost every operating room in the world and we're working with healthcare partners globally to help them understand the new EU MDR regulation and adapt how we work together to elevate the standard of care."

Jennifer Paine, VP Head of Global Regulatory Affairs, Johnson & Johnson MedTech

What's Changing for Me?

MDR will continue to ensure the quality, safety, reliability, and traceability of medical devices sold in the EU. It will provide greater transparency for patients and will require healthcare professionals to work in new ways. Here are some examples of what will change:

I'm a healthcare professional...

EU MDR brings changes for HCPs. As a trusted partner, JJMT will support our customers to understand the transition.

From MDD to MDR

EU MDR replaces the Medical Device Directive (MDD). Products that were previously MDD certified require reassessment to comply with EU MDR and achieve certification or CE Marking.

On 20 March 2023, the EU MDR 2nd Amendment Regulation (EU) 2023/607 came into force extending the transition period (until end of 2028 for low-risk and end of 2027 for high-risk devices), via the extension of the validity of legacy MDD certificates based on specific conditions.

MDD Devices compliantly placed on the market and fulfilling the EU MDR 2nd amendment conditions may continue to be made available or put in service until they reach their expiration dates.

Labelling

EU MDR labels are different from MDD labels (both can be placed on the market concurrently during and after the transition period). Label changes include, among others: the addition of the restricted substances symbol (if applicable), MD symbol and device lifetime details.

EUDAMED

The European Database on Medical Devices (EUDAMED) provides HCPs (and the general public) with access to medical device data via the website. This will include information on restricted substances, summary of safety and clinical performance for high-risk devices and implantable devices, classification, clinical investigations and CE certification documentation.

Patients also have access to the data in EUDAMED via this public facing website, making them more easily informed than ever before.

UDI

Health Institutions shall store and keep preferably by electronic means the UDI of the devices which they have supplied or with which they have been supplied, if those devices belong to class III implantable devices.

For devices other than class III implantable devices, Member States shall encourage, and may require, health institutions to store and keep, preferably by electronic means, the UDI of the devices with which they have been supplied.

Implant Card

Manufacturers will provide implant cards for MDR compliant and eligible implantable devices. Not all implants will be provided with an implant card, for example, sutures, staples, screws, and plates are exempt. HCPs complete them with the required info and give them to patients so they can access more info via the patient information leaflet website.

Product Availability

The changes associated with EU MDR could have consequences for the availability of medical devices and may drive portfolio changes. There may also be some supply continuity challenges. These types of disruptions are a constant feature as our industry contends with limited external EU MDR certification system capacity i.e., a backlog of medical device products awaiting review and EU MDR approval by Notified Bodies. We are also looking for longer term opportunities to expand our supply chain capacity. From JJMT's perspective, we have made a significant investment into EU MDR compliance and supply continuity to ensure we are well positioned to support our customers.

I'm a patient...

The biggest change for patients is the amount of medical device information they will have access to.

EUDAMED

Through the public EUDAMED website, patients can find information about medical devices available in the EU (https://ec.europa.eu/tools/eudamed).

This information will include details relating to clinical investigations, and safety or performance, classification, and restricted substances.

Unique Device Identification (UDI)

Devices must have a UDI which will identify the device in EUDAMED making it significantly easier to trace implanted devices and eventually monitor them post implant.

Implant Card

Patients will receive an implant card for some medical devices from their healthcare professional with important reference information regarding the device they are implanted with.

Electronic Patient information leaflet Electronic Patient Information (ePIL) website

Further information is available via a patient information website which is accessed using a reference code found on the implant card. The site provides information relating to the specific medical device implanted in simple, non-medical terms and includes warnings, precautions, and special measures to be taken.

When are these Changes Happening?

May 26, 2017

EU MDR came into force

May 26, 2021

EU MDR effective and mandatory

May 26, 2024

End of transition period for devices with valid MDD certs which do not transfer to MDR (and do not have a substitute device under MDR)

May 26, 2026

End of transition period for **class III custom-made implantables**

May 2027

May 2021 - May 2027

UDI: Staged application of the UDI to devices, and/or labels

Q4 2027

Mandatory usage required for four of six modules in EUDAMED (Actor Registration, Vigilance & PMS, Clinical Investigations, Market Surveillance)

The public can now access significant information for all 6 modules in EUDAMED

Dec 31, 2027

End of transition period for **High-Risk Devices**

Dec 31, 2028

End of transition period for **Low-Risk Devices**

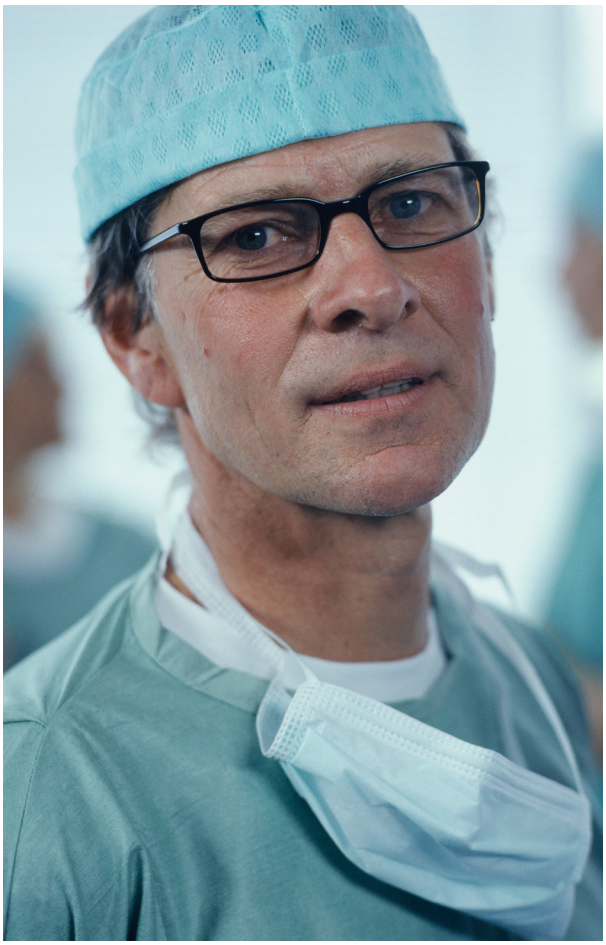
Q2 2029

EUDAMED mandatory usage required for remaining two modules: UDI & Device Registration and Notified Bodies & Certificates

EU MDR in Five

Here are five things you should know about EU MDR and JJMT...

1. In the future, medical device companies like JJMT will only be able to sell existing and future products in the EU if they are EU MDR compliant
2. JJMT has invested heavily in being ready for the change to continue meeting the highest standards of care
3. EU MDR is an opportunity to review our product portfolio to ensure we have the right products available in the right markets. A comprehensive range of products will be put through EU MDR compliance. Our active portfolio will be largely unchanged but will remain under constant review
4. EUDAMED is providing connectivity and visibility across previously disparate processes and data. It is not just about compliance – it is also about enhancing product and patient safety, a key premise of our CREDO
5. We are committed to supporting our customers and patients and have a dedicated website where you can learn more about EU MDR



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If you have questions, please contact your local customer service team or Johnson & Johnson MedTech sales representative. Alternatively, if you have any medical, scientific or technical questions please submit these questions to our Medical Affairs team via the Medical Information Requests (MIR) portal: Medical Information Request (MIR)

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