EUROPEAN UNION MEDICAL DEVICES REGULATION (EU MDR) PROGRAM

Frequently Asked Questions

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.

Here you will find answers to the most common questions you may have on EU MDR.

1. What are the key changes I am likely to see in the transition from MDD to EU MDR?

MDD and EU MDR largely share the same basic regulatory requirements

No existing requirements have been removed, but EU MDR adds new requirements.

- EU MDR places more emphasis on a life-cycle approach to safety, supported by clinical data
- EU MDR brings more stringent requirements to review Technical Documentation for the designated Notified Bodies
- Restricted Substances, if applicable, and Device Lifetime will now appear on product labels, as well as an MD symbol and UDI barcode
- In some cases, these increased requirements may drive portfolio changes for medical device providers. The feasibility and cost of meeting additional evidence requirements could also result in a change to product claims

EUDAMED will play a central role in making data available and increasing both the quantity and quality of data (more about this in question 10).

To respond to any further questions customers may have about this and/or strengthen your own understanding, we encourage you to read the EU MDR Fact Sheet.

2. How will EU MDR benefit our patients?

EU MDR will continue to ensure the quality, safety and reliability of medical devices sold in the EU and other global markets that accept the CE mark.

Patients will be able to access much more information about medical devices for example, implants.

Patients will receive an implant card per applicable product. If multiple implants are used during a procedure the HCP may choose to affix multiple labels to a single implant card as space permits.

Patients will also be provided access to electronic patient information leaflets (ePILs) via the implant card. This is a website which is an online patient resource that provides information related to the specific medical device implanted. The implant card contains a unique reference number (REF). When the patient inserts their unique reference number in the search bar on the website it will display:

- Information about the implant described in layperson's terms
- Warnings, precautions, or measures to be taken and expected lifetime

Another benefit for patients will be access to greater transparency through EUDAMED.

Guiding patients on how to go about accessing this information will be one of the primary changes for Health Care Professionals (HCPs) and Health Care Institutes (HCIs).

3. What will we have to do differently?

EU MDR requires HCPs to provide patients with implant cards, if applicable, for the specific device. These implant cards include a link to the Electronic Patient Information Leaflet Website (ePIL) that provides patients with relevant information about their surgery and the implanted device.

HCIs and HCPs will need to store UDIs for the devices they are using, per the EU MDR and national requirements.

HCIs and HCPs will be able to find information about specific medical devices in EUDAMED.

Depending on which country you're in, the Reprocessing of Single Use Devices will need to follow a certain quality management cycle if the HCI takes this task upon themselves.

Our Fact Sheet on the Reprocessing of Single-Use Devices in Hospitals / Health Institutions provides further information.

4. Can I still use MDD products that I have on shelf?

Medical devices compliant with the Medical Device Directive (MDD) remain available. The EU MDR transition period allows us to minimize disruption and ensure a smooth transition and patient access to the medical technologies they need.

Our EU MDR Fact Sheet provides further information on this transition and the implementation timeline for EU MDR.

5. Will product supply or availability be impacted in any way?

The changes associated with EU MDR could have consequences for the availability of medical devices.

Increased requirements may drive portfolio changes due to the overall cost of compliance.

There may also be some supply continuity challenges. These types of disruptions are a constant feature as our industry contends with limited external MDR certification system capacity i.e., a backlog of medical device products awaiting review and MDR approval by Notified Bodies.

We are also looking for longer term opportunities to expand our supply chain capacity.

From JJMT's perspective, we've made a significant investment into EU MDR compliance and supply continuity to ensure we're well positioned to support our customers.

6. Is there any impact on JJMT's product portfolio that I need to be aware of?

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 are being certified under EU MDR.

Our active portfolio will be largely unchanged but will remain under constant review.

Where we anticipate changes, we will communicate these in good time.

7. What JJMT products are impacted by EU MDR?

Products that were previously Medical Devices Directive (MDD) certified require re-assessment to comply with EU MDR.

The Medical Device franchises determine what products will be brought to EU MDR compliance allowing them to be sold in the EU market.

Changes to products such as labels and Instructions for Use (IFU) may impact global registrations even when the CE Mark is not utilized in that country.

8. What steps has JJMT taken to comply with EU MDR?

JJMT recognises the opportunities that EU MDR brings and sees the regulation as a new way of doing business.

As a company committed to patient safety, JJMT has always followed the highest standard of regulatory review.

Our size and scale have enabled us to proactively invest in EU MDR compliance and make us a key partner with EU MDR stakeholders.

Since 2017, a committed program team has been supporting EU MDR compliance with specific workstreams within the team addressing different parts of the requirement.

As your trusted partner, we will continue to communicate with you and support you by making you aware of how JJMT will operate in this new world.

9. How will I know the difference between current MDD and future EU MDR products?

MDD and EU MDR products may appear on the market at the same time. There is no overt indication on a product label or the product itself that tells if a product is MDD or EU MDR compliant. There are, however, subtle differences due to specific EU MDR requirements. For example, the presence of the MD symbol on the label is a specific EU MDR requirement and does NOT exist on MDD products.

Internally, J&J supply chain systems will utilize variants to identify MDD from MDR products.

Customers can continue to use current product numbers and GTINs for ordering product.

10. How will EUDAMED help us?

The creation of a European database on medical devices (EUDAMED) is one of the key aspects of the new rules on medical devices (Regulation (EU) 2017/745) and in vitro diagnostic medical devices (Regulation (EU) 2017/746).

EUDAMED will provide a living picture of the lifecycle of medical devices that are made available in the European Union (EU).

Set up by the EU Commission, the fundamental purpose of EUDAMED is to improve transparency, and collaboration among all stakeholders, including the public, with an emphasis on patient safety and clinical evidence.

EUDAMED is a secure web-based application comprised of a restricted site with six interconnected modules where relevant stakeholders create content.

- Actor registration
- Unique device identification (UDI) and device registration
- Notified bodies and certificates
- Clinical investigations and performance studies
- Vigilance
- Market surveillance

A public facing website is also available to provide access to a large portion of the information. This will strengthen confidence in the safety of medical devices available on the market.

The official web address of the EUDAMED public website is https://ec.europa.eu/tools/eudamed

Please click here to view the EUDAMED Fact Sheet.

11. What is UDI?

Unique Device Identifier (UDI) is a series unique numeric or alphanumeric codes created through a globally accepted device identification and coding standard.

UDI is required for all medical devices other than custom-made and investigational device.

It allows the unambiguous identification of a specific device on the market to:

- Facilitate easier identification and traceability of medical devices through the supply chain
- Significantly enhance the effectiveness of post-market safety-related activities
- Allow better monitoring by competent authorities
- Help reduce medical errors and fight against falsified devices
- Improve purchasing, waste disposal policies, and stock management by health institutes

Please click here to view the UDI Factsheet.

12. What is an electronic IFU/eIFU?

Instructions for Use (IFU) are provided with all medical devices and may be available in paper or electronic versions (eIFU). IFUs and eIFUs for medical devices intended for use by the Health Care Provider (HCP) and, with a few exceptions, are not provided to the patient.

While eIFUs are acceptable for all devices when coupled with a paper IFU, some products are eligible by EU law to no longer carry the paper version of the IFU. Instead, JJMT provides this document online via the JJMT website, www.e-ifu.com.

Medical devices eligible for eIFU in place of a paper IFU include:

- Implants & active implants and their accessories
- Fixed installed devices
- Devices with built-in systems displaying instructions
- software covered by the EU MDR

Please click here to view the IFU / eIFU Factsheet.

13. Where can I learn more about EU MDR?

In Q1 2023 JJMT will launch our own dedicated EU MDR page on the JJMT website to support our customers with the transition to EU MDR.

The EUDAMED Resource Center also provide a training page designed to educate HCI and HCPs on how to find information about specific medical devices for their patients.

The EU have also published their own guidance on the regulation. The EU MDR page can be found here.

Questions?

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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