Technical Bulletin

Understanding European Medical Device Regulation (EU MDR) in Relation to Rogers Material Compliance

As rules and regulations for medical and life science applications evolve, it is important to stay up to date on the latest information to understand the European Medical Device Regulation (EU MDR), its impact, and what information Rogers can provide to help customers be in compliance.

What is the European Medical Device Regulation (EU MDR)?

The European Medical Device Regulation is a set of rules and regulations that govern the clinical investigation and sale of medical devices for human use in the European Union.

Strengthening the regulatory procedures improves patient safety, increases device effectiveness, and enhances transparency in the medical device industry.

The EU MDR is a *device-level regulation.*

It consists of a wide range of requirements including classification, conformity, clinical evaluation, unique device identification, notified bodies, and post-market surveillance.

Does EU MDR impact me?

EU MDR went into effect on May 26, 2021. All medical devices for sale in the European Union must be certified under MDR.

For more information on Regulation (EU) 2017/745, visit www.eumdr.com/.

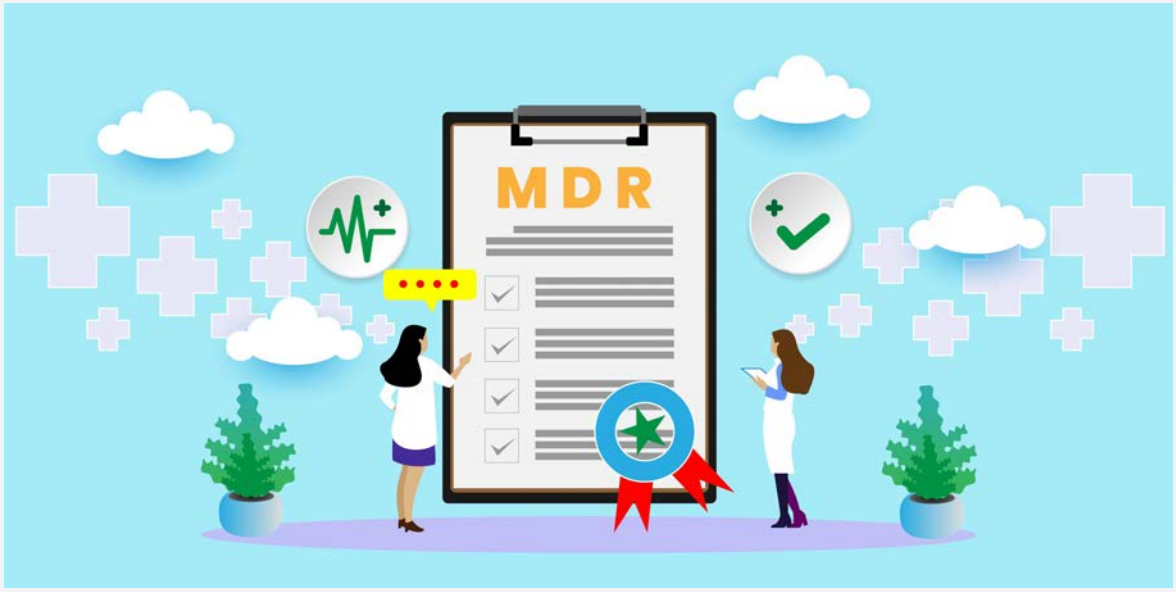
What applications fall under EU MDR?

EU MDR impacts a wide range of medical and life science devices for sale in the European Union, including diagnostic imaging equipment, surgical instruments, and software.

EU MDR does not include in-vitro diagnostics, as this is covered by the In-Vitro Diagnostic Device Regulation (IVDR), a related regulation.

How does EU MDR differ from a FDA regulation?

While similar in some respects, the EU MDR and FDA regulations differ in several ways, including technical documentation, classification, and clinical evaluation.



Do Rogers materials meet EU MDR?

Rogers does not certify materials to meet EU MDR as it *applies to the medical device itself, not the materials utilized in the construction of the device.*

While we do manufacture and supply the materials that go into devices, we cannot certify any of our materials to EU MDR.

We do, however, assist customers with any compliance requests.

What information does Rogers provide to help meet EU MDR compliance?

Rogers is committed to supporting OEMs by producing quality products, in a safe environment, that are manufactured with robust management systems certified to industry standards.

Detailed statements and certifications may be found at: www.rogerscorp.com/about-us/corporate-responsibility/certifications

Some BISCO® MS Solid Silicones are compliant with USP Class VI and some PORON® Medical Urethanes are tested for bio-compatibility, elements of ISO 10993.

What materials does Rogers offer for medical devices?

Rogers offers a variety of materials engineered to meet the demands of medical and life science applications, including silicones, polyurethanes, and PTFE films. Some of these materials include:

- BISCO® Silicones
- PORON® Polyurethanes
- DeWAL® PTFE Films

Contact a Rogers Sales Engineer for more Medical and Life Science application support, or visit **www.rogerscorp.com/markets/medical** to learn more.

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