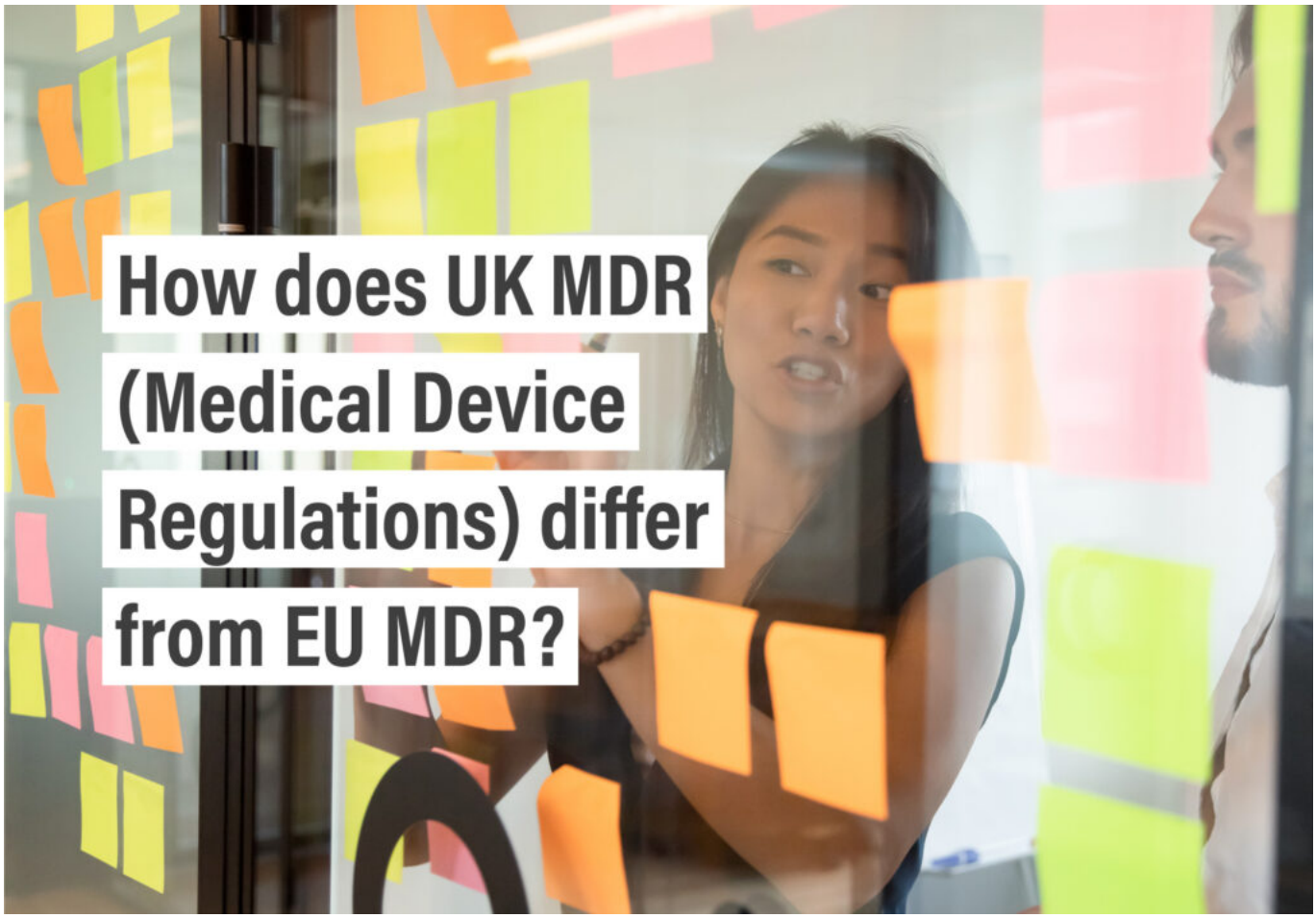
How does UK MDR (Medical Device Regulations) differ from EU MDR?



How does UK MDR (Medical Device Regulations) differ from EU MDR?

Reading time 8 mins

Key Points

- All medical devices placed on the Great Britain market (England, Scotland, Wales) need to be registered with the Medicines and Healthcare products Regulatory Agency (MHRA) as of 2021
- GB manufactured devices placed on the EU market before 1 January 2021 can stay on the market
- Non-UK manufacturers need to appoint a UK Responsible Person to act on their behalf to place products or medical devices on the UK market
- Conformité Européenne (CE) mark is required to demonstrate compliance with EU legislation
- UK Conformity Assessed (UKCA) mark is required to demonstrate compliance with GB legislation. From 1 July 2023, a UKCA mark will be needed to place a medical device on the GB market
- Both UK MDR and EU MDR need to have the necessary systems in place to handle (where required) clinical evaluations, quality management, post-market surveillance, and liability for defective devices

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When the UK withdrew from the European Union (a move otherwise known as 'Brexit´) in 2016, few sectors were unaffected. Healthcare, in particular, arguably felt the impact the hardest. Not only is it a sector where most companies operate across global regions as opposed to locally, but it's also the most heavily regulated. Developers and manufacturers can understandably get confused when ensuring UK medical devices regulations (UK MDR 2002) are met while ascertaining that they still comply with EU MDR – especially since the pandemic further disrupted the grace period given to transition. What are the key differences between UK MDR and EU MDR [1] [2] [3]?

1. The UK MDR, despite its name, only applies to countries in Great Britain (England, Scotland, and Wales)
2. In Great Britain (GB), medical devices must adhere to the UK MDR 2002; the EU MDR regulates Northern Ireland
3. From 2021, all medical devices placed on the GB market needed to be registered with the Medicines and Healthcare products Regulatory Agency (MHRA)
4. The UK MDR includes in vitro diagnostic devices (IVDs). In the EU, they are kept separate: EU MDR and EU IVDR
5. The EU MDR was put in place in 2017 and replaced the Medical Devices Directive (MDD 93/42/ECC) and the Active Implantable Medical Devices Directive (AIMD 90/385/ECC), with a transition period that ended in May 2021
6. Devices placed on the EU market before 1 January 2021 can stay on the market
7. Non-UK manufacturers need to appoint a UK Responsible Person to act on their behalf
8. UK Notified Bodies are now UK Approved Bodies and are needed where third-party conformity assessment is required
9. The EU no longer recognises UK Notified Bodies
10. Conformity certificates issued by EU Notified Bodies will continue to be valid for the GB market until 30 June 2023

Although medical devices placed on the GB market need to be registered with the MHRA, it's important to note that the MHRA does not provide any form of certification, accreditation, or approval for the device [4]. This is why conformity marking and getting your device certified are crucial.

What are the differences between UK and EU medical device conformity assessments?

Conformity assessments enable producers/developers to show that their device meets the relevant design, quality, and safety standards. At the same time, it assures consumers that they can be confident that what they're buying has been independently verified by an approved body. UK MDR conformity assessments differ from those for EU MDR:

1. Conformité Européenne (CE) mark is required to demonstrate compliance with EU legislation
2. UK Conformity Assessed (UKCA) mark is required to demonstrate compliance with GB legislation
3. CE marking will continue to be recognised and accepted in the UK until 30 June 2023
4. From 1 July 2023, a UKCA mark will be needed to place a medical device on the GB market
5. Devices sold in Northern Ireland will require both UKCA and CE markings
6. UK manufacturers of Class I medical devices (low risk medical devices such as adhesive bandages) and general IVDs can self-declare conformity before affixing a UKCA mark and placing their device on the market
7. Devices with a CE mark don't have to be re-labelled with the UKCA mark until 1 July 2023. Dual marking will continue to be accepted after that date
8. There are four UK MDR Approved Bodies that issue UKCA certification
9. 35 EU Notified Bodies issue CE certification

What do UK MDR and EU MDR have in common?

While some assert that the EU MDR are more stringent than UK MDR, both aim to prioritise patient safety without stifling medical device development and innovation. Other commonalities include [1] [2] [3]:

1. Both EU and UK medical devices are required to have a Unique Device Identification

(UDI) number to enhance traceability and the effectiveness of post-market safety-related issues
2. The number of the Notified (EU) or Approved (UK) body must appear on the device or product label
3. All devices must be classified appropriately
4. All product documentation and evidence of compliance must conform with the respective regulatory bodies
5. The necessary systems in place to handle (where required) clinical evaluations, quality management, post-market surveillance, and liability for defective devices

Are you ready to register your medical device?

If you have a medical device in development or are thinking about developing one, we hope this post has unravelled some of the complexities regarding UK and EU regulations. More information on the MHRA's registration guidance is available online, and we're also happy to provide some advice if what you're developing falls within our area of expertise.

With more medical device regulatory reforms on the horizon, we'll keep a close eye on possible impacts on our development process and the clients we serve. Are you a device engineer, software developer, or quality control manager struggling to navigate the regulatory landscape? You might find the medical device regulations glossary we put together helpful. Aside from that, we're always keen to share our experiences on all things regulations and compliance related – get in touch and lets chat!

We love to talk about new ideas

Do you have an idea? Book a consultation with an expert - it's free, it's confidential and there are no obligations.

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