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FPM Response to MHRA consultation on the indefinite recognition of CE marked devices

In February 2026, the Medicines and Healthcare products Regulatory Agency (MHRA) invited organisations to provide their views on proposals for the approach to recognising CE marked medical devices in Great Britain.

The MHRA invited views on the following proposals:

- Extending the current transitional arrangements for devices that comply with the Medical Device Directive (MDD) to align with the EU timelines for devices to transition from MDD to EU Medical Devices Regulation
- Indefinitely recognising devices that comply with the EU Medical Device Regulation (EU MDR) and EU in vitro Diagnostic Medical Devices Regulation (EU IVDR), and
- Introduction of an international reliance route for devices classified higher in Great Britan than in the EU.

FPM submitted its response (below) to the MHRA on 27th March 2026.

Questions

Proposal 1

Do you agree with proposal 1, which would extend the current transitional arrangements for devices that comply with the EU Medical Device Directive to align with the transitional timelines published by the EU?

Multiple choice answer:

- Yes
- No
- No opinion

Please use this space to explain your answer to the previous question (optional)

Yes — extending the transitional arrangements is a sensible and pragmatic approach. Aligning the UK timelines with the EU's updated MDR transition periods would help maintain regulatory consistency, reduce the risk of device shortages, and avoid unnecessary disruption to patient care. Many manufacturers are currently struggling to achieve MDR certification due to limited Notified Body capacity and the time-intensive process of resolving technical documentation nonconformities. As a result, companies are often prioritising MDR compliance solely for the EU market and may delay or forgo CE marking for the UK, reduce their device portfolios, or withdraw devices altogether. This could lead to fewer devices being available in the UK or to UK patients receiving products with lower performance or safety attributes.

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Extending the acceptance of valid MDD certificates on the GB market—while aligning with EU timelines—would therefore support supply continuity, maintain access to well-established devices with strong safety and performance histories, and provide manufacturers with a more realistic regulatory pathway. At the same time, this extension should be accompanied by strengthened MHRA oversight, particularly in relation to post-market surveillance and manufacturer compliance with GB requirements, to ensure that patient safety is not compromised during the transition.

More broadly, closer alignment and cooperation with the EU benefits UK patients and the healthcare system. International manufacturers primarily focus on the US, EU, and China; if the UK diverges too far from EU regulation, the UK's smaller market size means companies are less likely to invest the resources required to maintain UK-specific approvals. Harmonisation with the EU, coupled with active MHRA involvement in information exchange and safety monitoring, would therefore help sustain device availability, support regulatory stability, and uphold high standards of patient safety.

Proposal 2

Please note that we will only ask your views on proposal 3 if your answer to this question is "yes, for devices which would be classified the same, or lower, in GB (using the classification rules specified in the MDR 2002)".
Do you agree with proposal 2, which would indefinitely recognise devices that comply with the EU Medical Device Regulation and EU In Vitro Diagnostic Medical Device Regulation?
Multiple choice answer:

- Yes, for all devices
- Yes, for devices that would be classified the same or lower in GB
- No
- No opinion

Please use this space to explain your answer to the previous question (optional)

Yes — indefinite recognition of CE marked devices should be supported for products that would be classified the same or lower in Great Britain under the UK MDR 2002 classification rules. This approach is pragmatic and would help maintain patient access to safe and effective medical technologies while reducing unnecessary duplication in regulatory assessments. Given the significant alignment between the EU MDR/IVDR and the UK MDR (including proposed UK amendments), continued recognition of CE certified devices supports regulatory efficiency, market continuity, and timely access to innovation.

However, not all devices should automatically receive the same treatment, and some categories may warrant additional safeguards. While many devices will be adequately managed through aligned classification rules, there are situations where more stringent

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oversight may be necessary — for example, orphan or breakthrough devices, certain custom-made devices, or technologies entering the market with limited safety and performance data. In these cases, earlier access may be appropriate but should be accompanied by enhanced post-market data collection and strengthened performance and safety monitoring. Importantly, CE marked devices should not be required to produce substantially different evidence for the GB market than that expected under the EU MDR, as misaligned evidence expectations could discourage manufacturers from serving the UK market and risk limiting patient access to devices that already meet rigorous MDR standards.

Maintaining alignment in risk classification is essential to ensure that devices entering the GB market continue to meet appropriate safety, performance, and effectiveness expectations. At the same time, several regulatory considerations must be addressed to ensure that indefinite CE recognition does not weaken oversight:

- Some device specific requirements differ between the EU MDR and the UK MDR, even within the same classification (e.g., exempted Class IIb implants, well established technologies).
- A robust, enforceable mechanism must exist for the MHRA to restrict or remove devices from the GB market where safety or performance concerns arise.
- Reliance on vigilance reporting alone would be insufficient. Under-reporting is widely acknowledged, and vigilance is reactive rather than proactive.
- CE certified devices currently lack independent, GB specific regulatory oversight equivalent to that applied under UK certification pathways. EU Notified Bodies are not responsible for evaluating compliance with GB requirements or monitoring device performance in the GB market.
- Therefore, proactive post-market surveillance mechanisms tailored to the GB market must be introduced to ensure that emerging safety or performance concerns are identified promptly — particularly for devices with limited clinical evidence at the point of CE certification.

Overall, indefinite recognition of CE marked devices of the same or lower classification is reasonable and beneficial, but it must be supported by strengthened MHRA oversight, proactive post-market surveillance, and clear enforcement powers to maintain high patient safety standards while ensuring continued access to high quality medical devices.

Proposal 3 (only if answered Yes to proposal 3)

Do you agree with proposal 3, which would introduce an international reliance route for devices that comply with the EU Medical Device Regulation and EU In Vitro Diagnostic Medical Device Regulation where the risk classification is higher under MDR 2002?

Multiple choice answer:

- Yes
- No
- No opinion

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Please use this space to explain your answer to the previous question (optional)

Yes — an international reliance route could be appropriate for devices where the EU MDR/IVDR assigns a higher risk classification than the GB classification under the UK MDR 2002. However, the decision should not be based solely on whether the EU classification is higher or lower. Instead, it must be driven by the specific characteristics, clinical context, and risk profile of each device. A higher EU classification does not automatically mean a device requires a more demanding UK approval pathway and signalling that it does could unintentionally discourage manufacturers from seeking UKCA certification. This could result in companies focusing exclusively on the EU market, limiting availability of devices that already meet stringent EU MDR requirements and ultimately reducing access for UK patients.

A reliance pathway should therefore be designed to accommodate different categories of devices and ensure the appropriate level of scrutiny, without creating unnecessary regulatory barriers. This is particularly important for devices such as orphan or breakthrough technologies, custom made devices with limited premarket evidence, and products requiring enhanced performance and safety assessments. In such cases, earlier market access may be justified if accompanied by strengthened post-market data collection and more targeted UK specific surveillance obligations.

A separate reliance route could help tailor requirements to UK needs, including:

- Enhanced or differentiated post-market surveillance (PMS) for devices with limited initial evidence or where the UK population or clinical practice patterns warrant closer monitoring.
- Additional UK specific data expectations for novel or higher risk technologies — for example, AI driven devices, software as a medical device, implants with new materials or coatings, or device types where concerns have emerged internationally.
- Device specific or sector specific pathways, such as dedicated routes for AI/software, orthopaedic implants, vascular devices, or other high impact categories.

Where a device's classification is higher for the UK population or where GB specific risks are identified, either an international reliance route or full UKCA certification may be appropriate. Both approaches have strengths: UKCA certification ensures comprehensive oversight under UK MDR Part 4A, including active involvement of a UK Approved Body and clear mechanisms for restricting or removing devices where safety or performance concerns arise. A reliance route, meanwhile, allows the UK to leverage established EU MDR/IVDR regulatory assessments while maintaining appropriate oversight through MHRA monitoring and GB specific PMS obligations.

Overall, a flexible, risk-based reliance pathway — carefully designed to reflect device specific needs and UK healthcare priorities — would support patient safety, avoid

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unnecessary regulatory burden, and ensure continued access to high quality medical devices in the GB market.