

Medical devices regulations:

Consultation on the indefinite recognition of CE marked devices

C1. 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?

Yes (include short explanatory text if appropriate)

EuromContact strongly supports the extension of the current GB transitional arrangements for devices that comply with the EU Medical Device Directive to align with the transitional timelines published by the EU.

Contact lenses and lens care products that are legacy devices (class II non implantable) benefit from extended transition periods up to 31 December 2028. These products therefore continue to be lawfully placed on the EU market under the applicable transitional provisions.

A misalignment of even six months between GB and EU transitional deadlines would create significant regulatory and supply chain challenges. Manufacturers typically manage product certification, labelling, and distribution on a pan-European or global basis. Divergent timelines would require duplicate regulatory processes, separate inventory management, and could lead to premature GB-specific product withdrawals, despite continued lawful placement on the EU market. Such divergence would not enhance patient safety, as these devices remain subject to robust regulatory controls during the transition period, including post-market surveillance and compliance with applicable MDD requirements. To further support continuity of supply, for the purpose of the proposed extension, CE marked MDD compliant product already placed on the market in the EU ahead of the end of the transition period should also be considered placed on the market for Great Britain and be able to move freely to Great Britain after the end of the transition period.

Aligning GB timelines with those of the EU would ensure regulatory consistency and support continuity of supply and patient access in the GB, while maintaining appropriate safeguards for safety and performance.

C2. 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?

Yes, for all devices (include short explanatory text if appropriate)

EuromContact supports the proposal to indefinitely recognise devices that comply with the EU MDR, as this would promote regulatory alignment, reduce duplication, and support continuity of supply to the GB market.

This approach is consistent with principles of international regulatory reliance. The CE marking system is widely recognised as a robust and mature regulatory framework for medical devices, and several jurisdictions globally rely, in full or in part, on CE marking or EU MDR certification when granting market

access. Such an approach would not compromise patient safety in GB, as EU MDR certified devices are subject to robust regulatory requirements, including stringent conformity assessment procedures and ongoing Post-Market Surveillance (PMS). We recommend further consideration should also be given to ensuring alignment regarding PMS requirements as the proposed EU MDR PMS changes will lead to difference in the EU and Great Britain PMS requirements and increased regulatory burden in Great Britain with shorter adverse incident report timelines and PSUR frequency requirements.

In our specific case, contact lenses and lens care products are classified consistently between the EU and Great Britain. On that basis, we strongly support recognition at least for devices that are classified the same, or in a lower risk class, in GB compared to the EU. Given the scope of our sector, we are not in a position to take a definitive view on devices that may be classified differently in GB compared to the EU.

C3. 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?

No opinion