

MedTech Europe, ABHI and BIVDA welcome the indefinite recognition of CE- marked medical devices and IVDs in Great Britain

London and Brussels, 23 October 2026 – MedTech Europe, the Association of British HealthTech Industries (ABHI) and the British In Vitro Diagnostics Association (BIVDA) welcome the UK Government's decision, announced by the Medicines and Healthcare products Regulatory Agency (MHRA), to indefinitely recognise CE-marked medical devices and in vitro diagnostic medical devices (IVDs) in Great Britain.

Indefinite recognition of CE marked devices is a foundational step in UK regulatory reform towards ensuring continued patient access to essential medical technologies (including IVDs, digital healthcare and AI), providing greater regulatory predictability for manufacturers and supporting the competitiveness of the medical technology sector in both the UK and the EU.

The decision is also significant given the highly integrated nature of the EU–UK medical technology relationship. Our industries depend on interconnected supply chains, cross-border trade and close regulatory cooperation. Avoiding unnecessary regulatory divergence is essential to ensuring that medical technologies continue to reach patients and healthcare systems without disruption.

The continued recognition of devices compliant with the EU Medical Device Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) represents a pragmatic and proportionate approach. It maintains high standards of patient safety and device performance while avoiding unnecessary duplication of regulatory processes for products already assessed under the EU regulatory framework.

At a time when the medical technology sector is navigating an increasingly complex regulatory environment, this decision demonstrates the value of regulatory approaches that maintain high standards of safety and performance while facilitating market access and supporting innovation and investment.

MedTech Europe, ABHI and BIVDA appreciate the MHRA's constructive engagement with industry throughout the consultation process and welcome this outcome.

We look forward to continuing our constructive dialogue with the MHRA to support and monitor the effective implementation of this decision, including clear guidance for manufacturers. Continued regulatory cooperation between the UK and the EU will remain essential to ensuring patients, public and healthcare professionals have a more resilient supply of safe and effective medical technologies.

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About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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