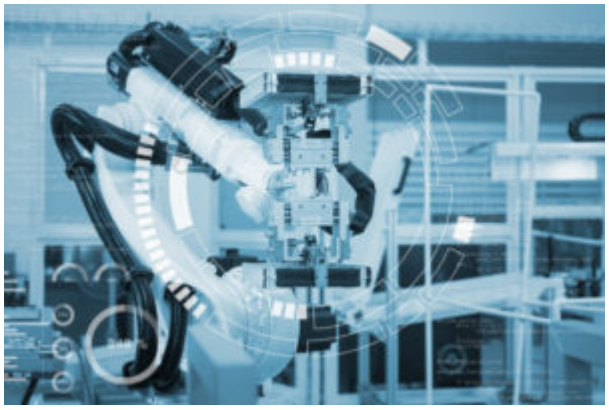
The MHRA Proposes to Extend the Period of Acceptance of CE Marked Medical Devices in Great Britain Beyond 30 June 2023



BACKGROUND

On 28 April 2023, the UK's medical devices regulator, the Medicines & Healthcare products Regulatory Agency (MHRA), announced its intention to extend the acceptance of CE marked medical devices in Great Britain (England, Scotland and Wales) beyond 30 June 2023.

Following the UK's departure from the EU, CE marked medical devices can currently be placed on the Great Britain market under the existing transitional arrangements until 30 June 2023. The proposed extension will support the ongoing safe supply of medical devices to Great Britain and ease the transition to the future regulatory framework for medical devices.

The government intends to introduce regulations in the future that will implement a substantial reform of the current regulatory framework for medical devices in the UK and is now aiming for core aspects of the UK's future regime for medical devices to apply from 1 July 2025.

PROPOSED EXTENSION TO TRANSITIONAL ARRANGEMENTS

The UK Medical Device Regulations 2002 (UK MDR) currently provide that the acceptance of CE marked medical devices on the Great Britain market will end on 30 June 2023. However, the MHRA intends to introduce legislation before 30 June 2023 which will provide that CE marked medical devices may be placed on the Great Britain market to the following timelines:

- General medical devices compliant with the EU medical devices directive (EU MDD) or EU active implantable medical devices directive (EU AIMDD) with a valid declaration and CE mark can be placed on the Great Britain market up until the sooner of (i) the expiry of the CE mark certificate or (ii) **30 June 2028**;
- In vitro diagnostic medical devices (IVDs) compliant with the EU in vitro diagnostic medical devices directive (EU IVDD) can be placed on the Great Britain market up until the sooner of (i) the expiry of the CE mark certificate or (ii) **30 June 2030**; and
- General medical devices, including custom-made devices, compliant with the EU medical devices regulation (EU MDR) and IVDs compliant with the EU in vitro diagnostic medical devices regulation (EU IVDR) can be placed on the Great Britain market up until **30 June 2030**.

The above extensions will not include class I medical devices and general IVDs (for which the

conformity assessment under EU MDD or EU IVDD did not involve a notified body), which can only be placed on the Great Britain market if the involvement of a notified body would be required under the EU MDR or IVDR (i.e., if it is an up-classified device or a reusable surgical instrument Class I device). Similarly, the extensions will not include custom-made devices that are compliant with the EU MDD or EU AIMDD, which can no longer be placed on the Great Britain market.

WHAT HAPPENS NEXT?

The legislation to implement the proposed extension will now be considered by the UK Parliament, and final approval is expected before 30 June 2023.