# UKCA and Future Routes to Market for Medical Devices in the UK

White Paper

# Introduction

Since the UK's withdrawal from the European Union and introduction of the UKCA mark, DEKRA has supported manufacturers placing medical devices on the UK market, while participating actively within Team-AB.

Today, repeated extensions to UKCA transition deadlines and the continued acceptance of CE-marked devices in Great Britain have resulted in limited uptake of UKCA certification across the industry.

Looking ahead, the future role of UKCA remains unclear. The UK Government has consulted on proposals including the indefinite acceptance of CE marking and the introduction of an International Recognition and Reliance (IR) scheme.

In this evolving context, DEKRA has taken the strategic decision not to offer UKCA certification services until a clear, and stable regulatory framework is established. This decision also aims to minimize unnecessary financial and operational burdens for manufacturers by preventing investment in certification routes that may be subject to significant change.

This whitepaper aims to outline the anticipated regulatory landscape and provide strategic guidance for approaching UKCA in the interim.

# Anticipated Regulatory Landscape

The UK Government and the Medicines and Healthcare products Regulatory Agency (MHRA) have signaled their intention to reform the UK medical devices regulatory framework. These reforms aim to streamline regulatory processes, improve efficiency, and align more closely with internationally recognised best practices, while maintaining a strong focus on patient safety.

Although many elements of the future framework remain under development, manufacturers should expect changes that affect conformity assessment routes, implementation timelines, and post-market compliance obligations. The reform programme formally commenced with the introduction of UK-specific Post-Market Surveillance (PMS) regulations in June 2025, with further regulatory changes anticipated from 2026 onwards.

**The evolving regulatory landscape can be broadly grouped into three key areas:**

- Changes to current UKCA framework
- Introduction of an International recognition and reliance scheme
- CE marking

# 3 Key Areas of regulatory evolution

1. **Changes to current UKCA framework**

- UKCA transition deadlines have been extended multiple times in response to industry concerns. Currently, CE-marked devices under (EU) Medical Device Regulation (MDR) and In-Vitro Diagnostic Regulation (IVDR) can stay on the Great Britain (GB) market until June 30, 2030, while those under older Directives (MDD/AIMDD/IVDD) have deadlines from June 30, 2028, or sooner if their certificate expires.
- Alongside CE recognition (see next section), the future UKCA framework will focus on offering an internationally competitive regulatory pathway for innovative devices.
- It is anticipated that the future UKCA regulation will include closer alignment with MDR/IVDR, in terms of classification of devices.

2. **Introduction of an International recognition and reliance scheme**

- To reduce duplication of regulatory assessments, accelerate market access in Great Britain, and reduce administrative burdens a new scheme will be introduced. This is intended to recognise medical devices that have already been authorised by comparable regulator countries (CRCs) such as Australia, Canada, and the US.
- Eligibility depends on device classification and previous authorisation by the CRC.
- While MHRA have not published any dates for the availability of this route, it is anticipated that the operational processes, necessary to establish this route are expected to delay its availability until no earlier than mid-2027.

3. **CE marking**

- Due to market pressure, the MHRA plans to consult on the Indefinite acceptance of CE marked medical devices. This consultation is due to begin in early 2026.
- It is anticipated that indefinite acceptance will be approved and enacted before the existing UKCA transition periods end, ensuring seamless entry into the UK market for MDR/IVDR certified devices.

The role of the UKABs in the above UKCA, IR and CE marking routes to market remain unclear at this point.

# Strategic Considerations for UKCA Market Access Planning

**Until the new frameworks are finalized, manufacturers have several options to consider, depending on your UKCA adoption status:**

- UKCA not yet implemented
  - Postpone UKCA certification to avoid unnecessary costs until revised requirements and timelines are confirmed.
- Portfolio includes UKCA and CE certified devices
  - Use your CE mark to access UK market to avoid unnecessary cost and check-out the conditions with MHRA.
- Portfolio includes UKCA only certified devices
  - Engage with your UKAB to understand their plans and approach to upcoming changes.

more information about market access in the UK can be found on the MHRA website here

If you have any specific questions, we recommend contacting the MHRA for guidance on your situation, as they take a pragmatic approach to managing UKCA certification and any changes (such as a transfer of a UK Approved Body) within the evolving regulatory framework.

# **Planning** future entry into **UK market with DEKRA**

Until the new regulatory frameworks are clear, we advise manufacturers to consider MDR/IVDR certification as a route that currently provides assured access to the UK.

Our shared goal is to keep safe and compliant devices on the market while ensuring a smooth transition to the new framework.

We remain dedicated to supporting manufacturers access the UK market and intend to offer UKCA certification once a clear and stable regulatory framework is established.

We will continue to monitor UK regulatory developments closely and provide updates to help you navigate this evolving landscape.

# Contact us for more information

Talk to our experts