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, full membership of the Medical Device Single Audit Program (MDSAP), 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 the UK Government has confirmed that it will introduce an international recognition framework for medical devices. The framework will allow the MHRA to rely, where appropriate, on approvals issued by comparable regulators in-Australia, Canada, the European Union, and the United States, while retaining the authority to refuse applications where the supporting evidence is considered insufficient .
- The route available under the international recognition framework will depend on a device's UK risk classification, the comparable regulator that authorised the device, and the regulatory pathway used in the originating jurisdiction. Depending on these factors, manufacturers may qualify for simplified registration for certain low-risk devices or reliance-based assessment pathways for higher-risk devices. The framework will be implemented in phases as part of the UK's wider programme of medical device regulatory reform, with operational rollout expected to continue through to mid-2027.
- In parallel, the MHRA has announced its intention to progress toward full membership of the Medical Device Single Audit Program (MDSAP), reflecting a broader move toward increased international reliance on established regulatory systems and quality management system audits (see also next page).

3. CE marking

- The UK Government has confirmed its intention to permit the Indefinite acceptance of eligible CE marked medical devices. This policy is intended to maintain patient access to medical technologies, reduce regulatory burden and provide manufacturers with continued access to the Great Britain market without requiring UKCA marking where CE certification is accepted. The role of UK Approved Bodies (UKABs) within the future regulatory framework, including alongside the UKCA and international recognition routes to market, is expected to evolve as the new legislation is implemented.

Greater International Alignment

MHRA Moves Toward Full MDSAP Membership
In June 2026, the UK's Medicines and Healthcare products Regulatory Agency (MHRA) announced its intention to progress toward full membership in the Medical Device Single Audit Program (MDSAP), reinforcing its commitment to international regulatory cooperation.

What MDSAP Means
MDSAP allows a single quality management system audit to satisfy the requirements of multiple participating medical device regulators, helping reduce audit duplication and improve efficiency for manufacturers.

Potential Impact on UK Regulation
The MHRA is assessing how MDSAP could be incorporated into the future UK medical device framework while maintaining Great Britain-specific requirements. This may influence future approaches to UKCA conformity assessment, quality management system oversight, and regulatory recognition.

DEKRA's Perspective
As an authorized MDSAP Auditing Organization, DEKRA supports manufacturers seeking compliance across participating jurisdictions. Greater MHRA engagement with MDSAP could enhance regulatory efficiency, strengthen international alignment, and create benefits for manufacturers operating in multiple markets.

MDSAP provides a harmonized framework for QMS audits; however, it is unclear how the MHRA envisions addressing product-specific reviews (technical documentation reviews), alongside the MDSAP audit approach.

Looking Ahead
For manufacturers pursuing UKCA certification, this development highlights the UK's ongoing move toward international harmonization while preserving national regulatory autonomy. Companies already participating in MDSAP may be well positioned to benefit from future regulatory efficiencies as the framework evolves.

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.

Manufacturers may also wish to consider participation in the Medical Device Single Audit Program (MDSAP), where applicable, as a potential means of supporting future alignment with international regulatory reliance pathways.

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 encourage manufacturers to consider MDR/IVDR certification as a route that currently provides assured access to the UK. Manufacturers participating in MDSAP, or considering participation, may also be strategically positioned should the MHRA decide to incorporate MDSAP outputs into future regulatory processes.

As an authorized MDSAP Auditing Organization, DEKRA is well placed to support manufacturers pursuing both international market access and future UK regulatory opportunities.

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