UKCA guidance for medical device products from DEKRA

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On the safe side.

New regulations, roles and changes relevant to placing medical devices on the UK market with the introduction of UKCA marking.

With the United Kingdom (UK) leaving the European Union (EU), changes came into force for manufacturers placing medical devices on the UK market. As of January 1, 2021, a new conformity assessment marking scheme - called UK Conformity Assessed (UKCA) marking - was launched in Great Britain (England, Wales and Scotland) instead of the CE mark. It will become mandatory as of July 1, 2023.

UKCA marking at a glance

- UKCA marking will be mandatory from July 1, 2023. However, manufacturers will be able to apply UKCA marking to their products from January 1, 2021.
- The UKCA mark will not be recognised in the European Economic Area (EEA) and will not be recognised in Northern Ireland. In both markets, EU CE marking is required. To place products on the market in the EEA and/or Northern Ireland manufacturers need CE marking.
- EU Notified Bodies can perform conformity assessment for CE marking according to their designation, but cannot issue UKCA marking.
- New UK Approved Bodies will be designated by MHRA to perform conformity assessment for UKCA marking. UK Approved Bodies cannot perform conformity assessment for CE marking. This means, manufacturers will require conformity assessment under an EU Notified Body and a UK Approved Body to place product on the market in both Great Britain and the EEA plus Northern Ireland.
- The existing UK Notified Bodies will roll over to become UK Approved Bodies for UKCA marking, but have lost their designation as EU Notified Bodies for CE marking.

- CE marking will continue to be recognised until June 30, 2023.

Although UKCA marking can be used from January 1, 2021, it is not mandatory until July 1, 2023. This means certificates issued by EU-27 Notified Bodies, including DEKRA, will continue to be valid in the UK for the next two and a half years.

- Regulatory roles and responsibilities changed

The role of the UK regulator Medicines and Healthcare products Regulatory Agency (MHRA) will include oversight of all devices on the UK market and will implement vigilance, sampling, and reporting activities, as well as managing incidents.

- UK Market Regional split.

From July 1, 2023, there will be a split in the UK requirements: Great Britain (England, Wales, and Scotland) will have a single new approach and UKCA marking will be mandatory.
Northern Ireland will have a level of duality, spanning the requirements for Great Britain and the requirements EU. CE marking will be mandatory.

- Medical devices require registration with MHRA.

Manufacturers in the UK (Great Britain and Northern Ireland) can register directly with MHRA, but manufacturers outside of the UK will need a UK Responsible Person to perform registration. Registration deadlines depend on the risk classification of the device.

Action needed for manufacturers of medical devices

The changes that result from Brexit mean that manufacturers will need to examine their portfolios and take required actions to ensure continued market access after the two-and-a-half-year transition period ends on July 1, 2023.

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The actions will depend on:

- Where devices are placed on the market, considering the EEA, Northern Ireland and Great Britain separately. This will determine whether CE marking, UKCA marking or both markings are required for the products.
- The risk-class of the medical product, as this determines when the devices need to be registered with MHRA and, accordingly, when a Responsible Person needs to be appointed

Labelling requirements

From January 1, 2021 through to June 30, 2023, all devices placed on the market in Great Britain must bear either a valid CE marking or a valid UKCA marking.

From July 1, 2023, the UKCA marking is mandatory on the labelling. A UK Approved Body will be required for UKCA marking in the same way that an EU Notified Body is, and will be, required for CE marking. Labelling requirements for the UKCA marking include the UKCA mark with the UK Approved Body number.

Roles & responsibilities

Within the new UKCA guidance, there are some new roles and responsibilities including:

- Registration with the MHRA
- Appointment of a Responsible Person
- Appointment of an Authorised Representative

Registration with the MHRA

The MHRA will have oversight of all devices on the UK market and will implement vigilance, sampling, and reporting activities as well as managing incidents.

Devices for the UK market (including Northern Ireland) need to be registered with MHRA.

The registration requirement comes into effect from January 1, 2021, but there is a "grace period" depending on the risk classification of devices. This means that not all devices require registration by January 1, 2021.

Manufacturers in the UK can register directly with MHRA, but manufacturers outside of the UK will need a UK Responsible Person to perform registration.

Appointment of a Responsible Person

The appointment of a Responsible Person is mandatory from the moment that the registration requirements apply. We recommend that you consider this requirement as soon as possible.

Manufacturers based outside of the UK will need a UK Responsible Person to place a device on the market in Great Britain and Northern Ireland.

The UK Responsible Person role is similar to that of the EU Authorised Representative for manufacturers outside of the EEA. When the manufacturer is based outside of the UK and places product on the market of Great Britain or Northern Ireland, the UK Responsible Person will assume the responsibility of the manufacturer for the product in the UK including registration of the devices with MHRA.

Manufacturers based outside of the EEA who have an Authorised Representative will also need a Responsible Person. The duality of the market arrangement for Northern Ireland means that an EU Authorised Representative in Northern Ireland can act as both an EU Authorised Representative and a Responsible Person, representing the manufacturer in the jurisdictions of the EU, Great Britain and Northern Ireland. However, an EU Authorised Representative outside of Northern Ireland will not have this same duality.

There are some specific differences where the market is limited to Northern Ireland, see below.

The role of the Responsible Person is to ensure that the declaration of conformity and technical files have been prepared and where third-party conformity assessments are required, they have been performed. The Responsible Person will need a copy of the technical file and the declaration of conformity, and any associated certificates.

The Responsible Person will liaise with MHRA on behalf of the manufacturer responding to requests for documentation and managing communication between MHRA and the manufacturer, including requests for samples from the market or access to the device.

The manufacturer needs to have a contract with the Responsible Person and if the contract is terminated, the Responsible Person is required to inform MHRA and the UK Approved Body certifying the device, where applicable.

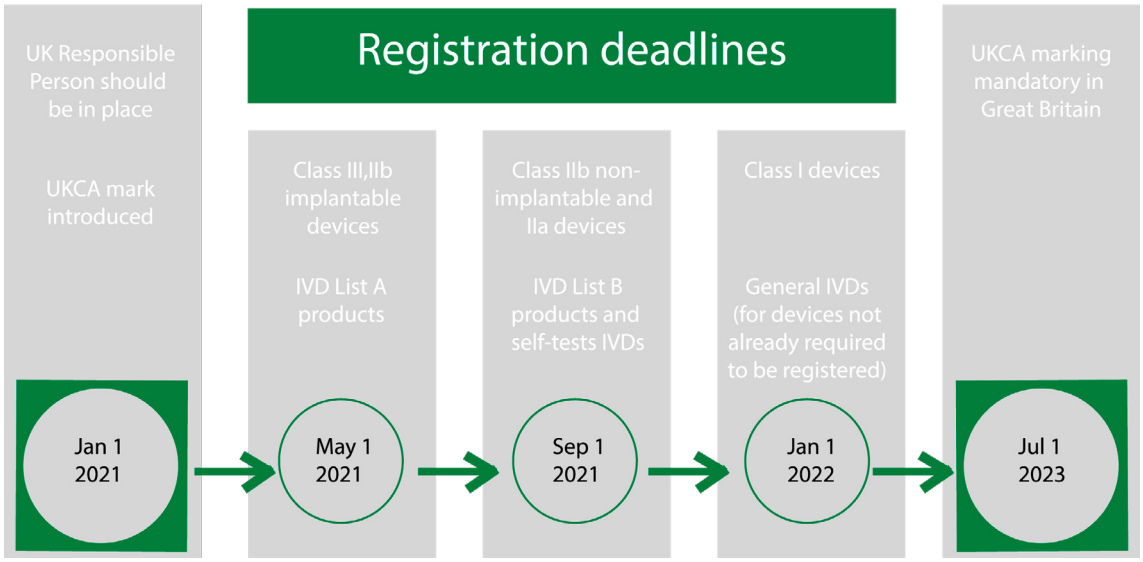
Appointment of an Authorised Representative

Manufacturers in Great Britain must appoint an EU or Northern Ireland-based Authorised Representative to place product on the market in Northern Ireland and/or the EU. For manufacturers in Great Britain, they will need an EU Authorised Representative to place product on the market in Northern Ireland, as well as the rest of the EEA; but they do not need a UK Responsible Person.

Regulations within the UK

For both Great Britain and Northern Ireland, MHRA is the Competent Authority. However, the UKCA marking that will become the mandatory route to market in Great Britain will not be recognised in Northern Ireland: Northern Ireland will continue to recognise CE marking. This means that UK manufacturers placing product on the entire UK market will require both CE marking and UKCA marking. Indeed, the only manufacturers that require UKCA marking alone are manufacturers in Great Britain only placing product on the home market (England, Wales and Scotland).

UKCA marking timeline



UK Statute Book

The EU legislation for medical devices on the UK statute book at the end of the Brexit transition (December 31, 2020) is retained until June 30, 2023.

From January 1, 2021 through to June 30, 2023, there is a transition period where the UK will operate under the legislation that was on that statute book at the end of the transition period. This means that because the Regulations have not reached their date of application (May 26 2021 for the MDR 2017/745 and May 26 2022 for the IVDR 2017/746), they are not on the UK statute book and, therefore, will not be retained by the UK.

The UK Approved Bodies will only be able to perform conformity assessment to the UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002). This UK regulation is not the same as the EU MDR and IVDR. The Medical Device Regulation 2002 covers all medical devices with conformity assessment based on the EU Directives:

- Directive 90/385/EEC on active implantable medical devices (EU AIMDD)
- Directive 93/42/EEC on medical devices (EU MDD)
- Directive 98/79/EC on in vitro diagnostic medical devices EU IVDD)

This means that the effective legislation moving forwards from January 1, 2021 and until the end of the two and a half year transition period will be based on the EU Directives and UK conformity assessment process leading to UKCA marking on products will based on the requirements of the EU Directives.

DEKRA can support you

At DEKRA, we are committed to supporting our customers through the changes that have resulted from Brexit. This means providing updates on the requirements and also working on the establishment of a robust UKCA conformity assessment process that minimises duplication of activities and disruption.

Before June 30, 2023, there are some changes for our CE marking customers that will require both CE marking and UKCA marking including, but not limited to:

- A separate contract for the UKCA conformity assessment activities directly with our DEKRA UK legal entity
- Additional audit and Technical Documentation (TD) review requirements
- New certification activities

It is worth noting that the date of application of the new EU Regulations falls within the UK transition period (from January 1, 2021 until June 30, 2023). This means that the route to market requirements for the EU and Northern Ireland, giving market access to the EEA and Northern Ireland, will be based on the new EU Regulations, whereas in Great Britain these requirements will be based on the EU Directives that the Regulations replaced. At this moment it is not clear whether the EU Regulations will be adopted in Great Britain after the transition period ends.

As with the adoption of the EU Regulations, DEKRA will support manufacturers who wish to continue with pre-Brexit marketing strategies that placed product on the market across the UK, or in both Great Britain and other EEA countries.

Existing customers of DEKRA

DEKRA has extensive experience with both the EU Regulations and EU Directives and, with its UK office near London, is applying to become a UK Approved Body to deliver UKCA marking services. After designation in the UK (expected mid-2022), DEKRA will be able to provide CE marking and UKCA marking services.

DEKRA will be able to provide a plan for the additional activities needed for our existing CE marking customers once DEKRA is designated by MHRA to deliver UKCA marking. To avoid duplication and disruption, where possible we will combine additional activities for UKCA marking with those already scheduled in your service plan.

New customers of DEKRA

After MHRA designation, DEKRA will be able to offer a combined CE marking and UKCA marking package. Where both routes to market are required, we recommend following the CE marking route with one of our two EU 27 designated Notified Bodies and the UKCA marking route could be offered in parallel.

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