FRIWO

WHITE PAPER

The UKCA Guide

What manufacturers of technical products and medical devices need to know about the UK's new marking scheme

Introduction

The UK's exit from the EU Customs Union and European Single Market on 1st January 2021 will have massive implications for many trading partners. In addition to the increased documentation and control effort due to the new customs regulations for exports and imports, this primarily affects manufacturers with regard to product safety regulations.

Within the EU Single Market, all products that comply with harmonised product safety directives bear the CE marking (Conformité Européenne). Since then, the "European Conformity" marking has ensured that a technical product or medical device complies with all specified product safety standards within the EU and can therefore be freely traded in the participating states of the European Economic Area (EEA).

In recent years, the EU has devised a detailed system for how manufacturers, distributors and importers can circulate products with a CE marking. Although this marking requirement involves a certain amount of organisational effort, it greatly simplifies cross-border trade in electronic and medical devices throughout Europe.

Thanks to Brexit, the UK left this system on 1st January 2021. The British government has put its own solution in place of the CE marking, namely the UKCA marking. For companies from the EU, this means that in the future they will have to familiarise themselves not only with CE certification but also with the British model of UKCA marking if they want to offer products covered by this standard on the British market.

In this guide, we explain what the deadlines are for this transition, what is different from the old CE marking, how UKCA certification works for the UK and how to use the marking.

Looking at the Economy

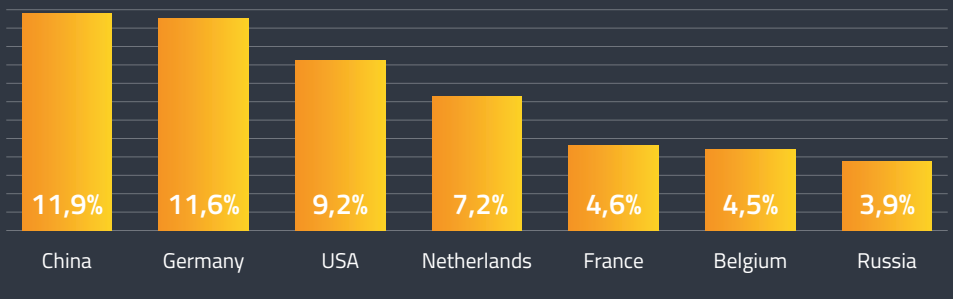
What is the expected economic impact of UKCA implementation?

In a survey conducted by the consultancy firm KPMG in the spring of 2021, many German and British companies stated that they have an even more negative assessment of the consequences of Brexit after the first three months than they did before. The introduction of UKCA marking is just one more negative factor in the mounting administrative and logistics workload that is hindering German-British trade as a result of Brexit..

German companies trading with the UK see themselves at a disadvantage compared to domestic competitors due to the newly added regulations. According to the KPMG study, one in six companies plans to cease foreign trade with the UK.

Which countries have the largest export volume to the United Kingdom?

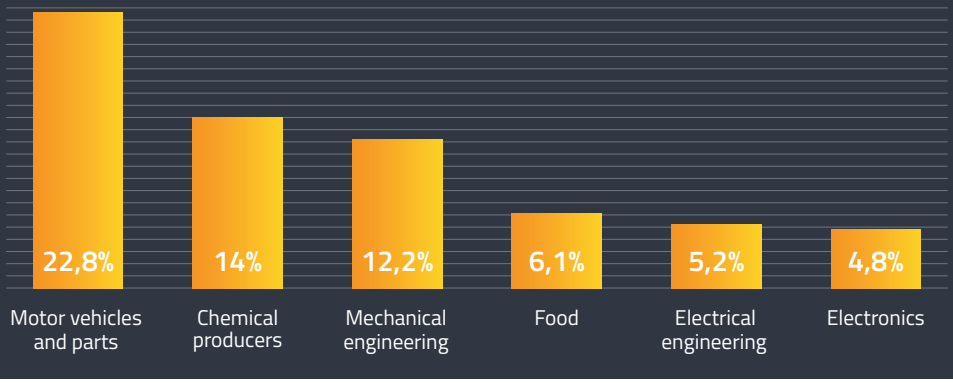
The UK imported $631.2 billion worth of goods in 2020. Here's a list of the main supplier countries as a percentage:



Source: GTAI

Which industries are directly and indirectly affected by the UKCA?

The UKCA marking directly affects all products and product groups for which the CE marking was previously mandatory.
The sectors in Germany that are most affected indirectly by the UKCA are those that export the most goods to the UK. As a percentage, these are:



Source: GTAI

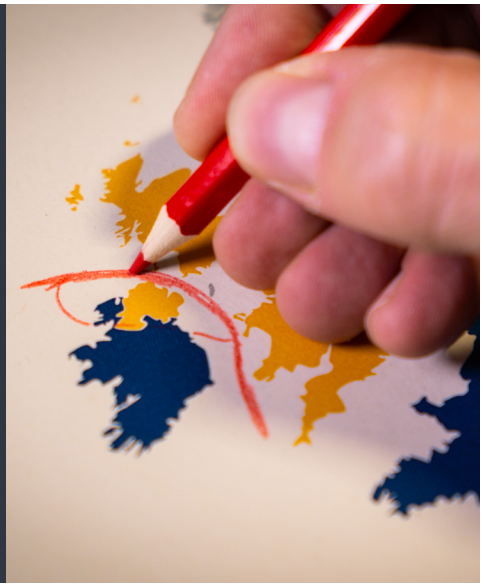
UKCA: What Companies Need to Know Now

What is UKCA intended to do?

The UKCA marking stands for "UK Conformity Assessment". With this marking, manufacturers must guarantee that products brought onto the market in England, Scotland or Wales comply with the applicable product regulations and standards in the UK. The British government has largely adopted the content of the EU's product safety regulations and standards and incorporated them into its own legislation.

Special arrangements for Northern Ireland

Northern Ireland has a special status as the CE marking remains valid for the vast majority of product groups. It's also possible to mark products with a UKNI mark, which is particularly useful for British companies that export their products to the Northern Irish market



When does UKCA come into force?

Officially, the UKCA marking came into force when the UK left the European Single Market on 1st January 2021. However, to make the changeover more seamless for market players, the British government has set the following transition periods. On August 24, 2021, the Department for Business, Energy & Industrial Strategy announced that the following deadlines would apply:

- Most products can be marketed with a CE marking or the new UKCA marking in England, Scotland and Wales by the end of 2024.
- From 1st January 2025, a conformity assessment under the new UK regulations will be mandatory for most products currently covered by the CE marking. These products will then have to bear the UKCA marking in order to be traded in England, Scotland or Wales.

Which products with CE marking are covered by the deadline extension until the end of 2024?

The deadline of the end of 2024 applies to all products with CE markings, the basis of which:

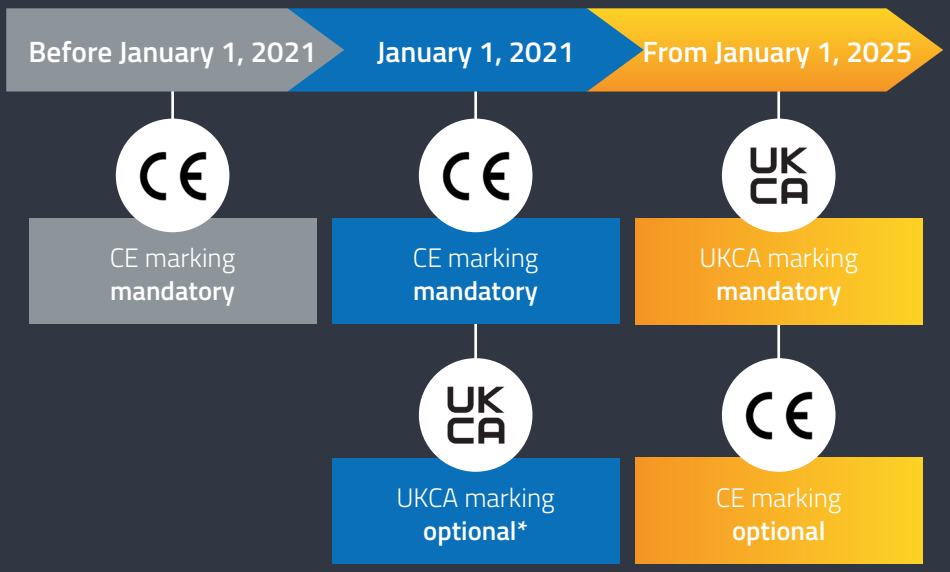
- Is a self-declaration,
- Is based on conformity assessment by an EU Assessment Body or conformity assessment by an accredited body outside the EU,
- Is a certificate of conformity issued by a body in the UK whose approval was transferred to a corresponding body in the EU before 1st January 2021,
- As well as for all products with CE marking that are already available on the UK market.

This regulation only applies as long as the requirements for marking in the EU and the UK are the same. The British government points out that there are currently no plans to issue different regulations. However, if the EU were to change individual regulations, this would also be the case.

Which products are not covered by the deadline extension to 1st January 2025?

All new products that fall under the UKCA marking and require a third party conformity assessment to be carried out by a UK body must already be marked with the UKCA marking from 1st January 2021.

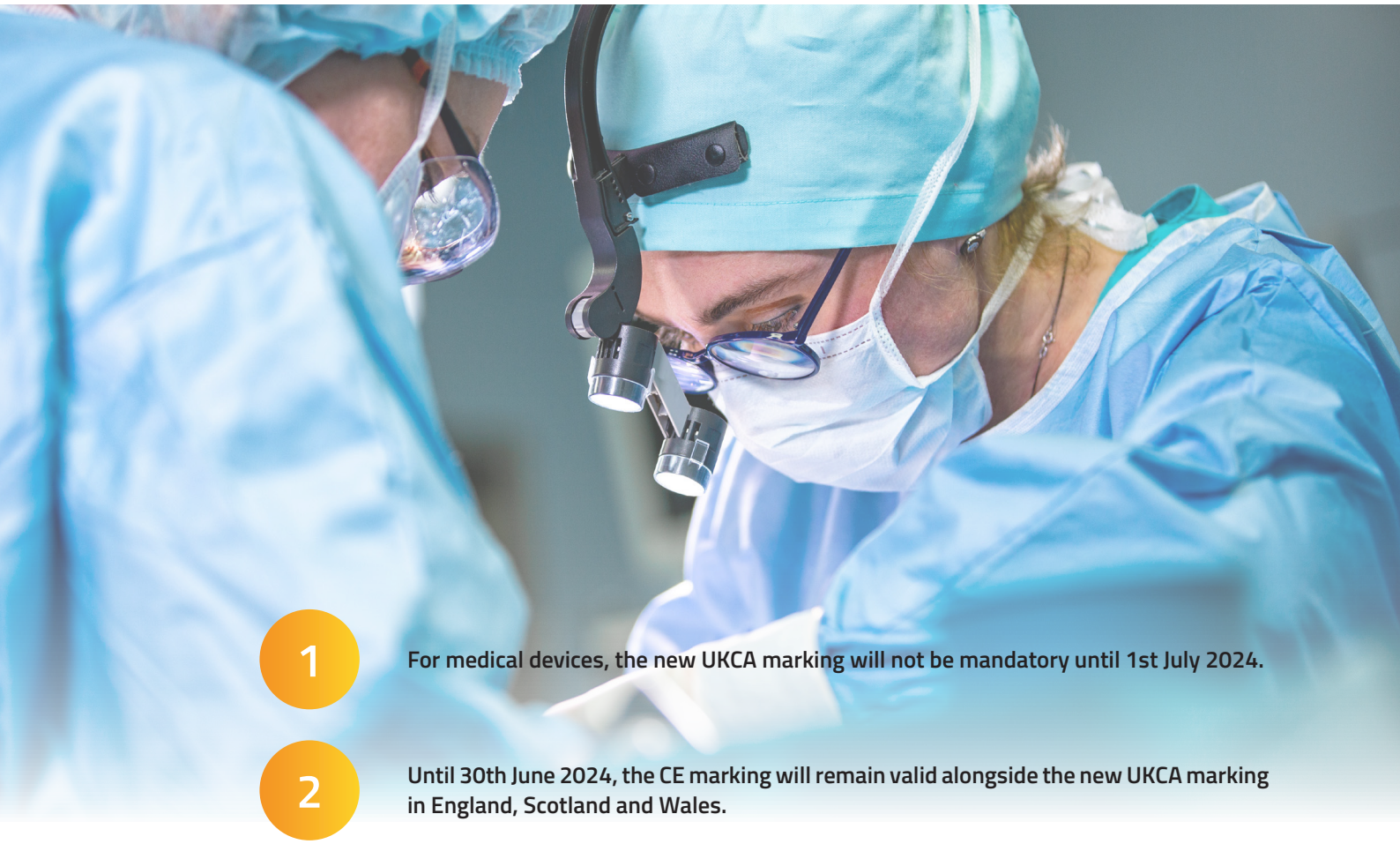
The Course for Products in the UK



* mandatory for certain products: see information in text

Exemptions for medical devices

In order to ensure that the British healthcare system is supplied during the transition period, the British government issued an additional regulation for medical devices with separate transition periods. The main points are as follows:



1. **For medical devices, the new UKCA marking will not be mandatory until 1st July 2024.**
2. **Until 30th June 2024, the CE marking will remain valid alongside the new UKCA marking in England, Scotland and Wales.**
3. **Conformity assessments of recognised bodies from the EU are still valid within this period until 30th June 2024.**
4. **In order to bring a product to the UK market, manufacturers must set up a new process: As of 1st January 2021, all medical devices must now be registered with the Medicines and Healthcare products Regulatory Agency (MHRA).**
5. **Exceptions to this deadline apply to Class IIIs and Class IIb implants, active implantable medical devices, and in vitro diagnostic (IVD) devices on List A (1st May 2021); Class IIb and IIa devices and devices and IVD devices on List B and self-test IVDs (1st September 2021); Class I devices, custom devices and general IVDs, (1st January 2022).**
6. **As an EU manufacturer, you must appoint a "UK Responsible Person" to assume responsibility for the product in the UK market.**

The Certification Process

What is changing?

During Brexit negotiations, the UK had set itself the goal of reaching a Mutual Recognition Agreement (MRA) with the EU on product marking. However, the EU rejected this. As a way out, the UK developed its own set of regulations with the UKCA marking, which is strongly aligned with the CE marking in terms of content.

For manufacturers, this means that for most products – as things stand today – the standards of the CE and UKCA markings remain identical, i.e. they must meet the same basic requirements. In other words, the technical standards that products must meet in order to obtain market approval in the UK will remain largely unchanged. However, what does change is the certification process that a product must undergo in order to obtain the UKCA marking.

UK Market Conformity Assessment Bodies: the New Assessment Bodies

The procedure for obtaining the UKCA marking will continue to be carried out by an accredited Conformity Assessment Body (CAB). However, this now requires new accreditation by the British government. To obtain this approval, the British government has established an important formal criterion: the body's registered office must be in the UK.

All officially accredited bodies (UK Approved Bodies, UK Notified Bodies) of the old CE certification based in the UK have thereby automatically received the new accreditation. The same applies to all conformity assessment bodies already registered in the UK, such as recognised third party organisations (RTPOs), user inspectorates (UIs) and technical assessment bodies (TABs).

During the transition period, it may be permitted in some cases for products to obtain a UKCA marking based on joint certification by Assessment Bodies in the UK and EU.

How does the certification process work?

The certification process for the UKCA marking goes through the same six steps as the CE marking process:

1. Determine which directives and standards your product generally falls under in the UK.
2. Record exactly which of these directives and standards apply to your product.
3. Check whether an independent conformity assessment must be carried out for your product and, if so, which body is responsible for this.
4. Conformity assessment by an appropriate UK accredited body.
5. Preparation of technical documentation.
6. Preparation of the Declaration of Conformity and application of the UKCA marking.

When should manufacturers start UKCA certification?

As UKCA certification is already valid, companies should start as early as possible to initiate the certification process to UKCA standards for all products to be exported in the UK. In our experience, once all the necessary documents are in place, certification is relatively quick in most cases. However, you should keep in mind that a lot of companies currently need to have their products certified for the UK. Therefore, you should expect delays at the relevant offices due to these special circumstances.

The UKCA Marking

What does the UKCA marking look like?

Where and how must the UKCA marking be placed?

If possible, the UKCA marking should be placed directly on the product or – if this isn't possible – on the packaging. If not, it can also be printed in a manual or other accompanying documentation in exceptional cases. More detailed provisions may be governed by the relevant product regulations.

The minimum height of the UKCA marking is 5mm. Other minimum sizes may apply to individual product types. When changing the size of the UKCA marking, the proportions of the letters to each other must always be maintained. The marking must be applied legibly, but can be changed graphically, e.g. the colour.

What other information must be provided?

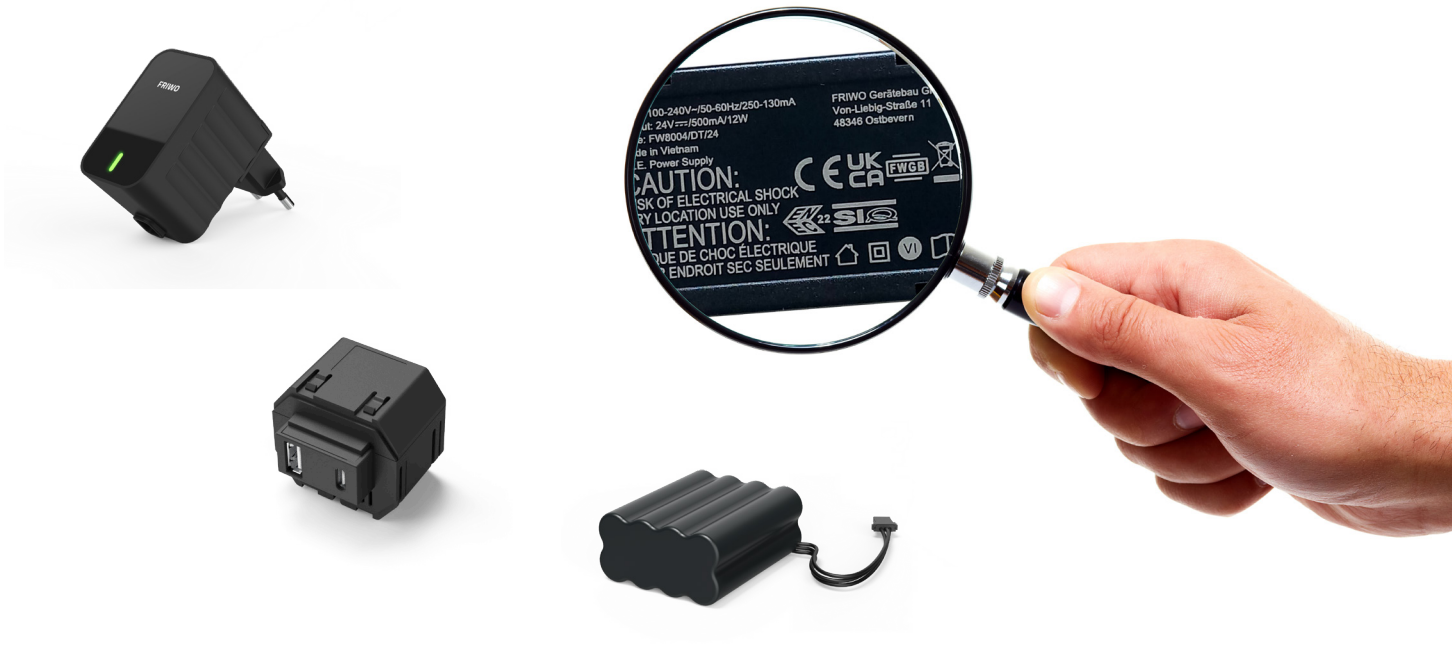
Most products with a UKCA marking require an accompanying "UK Declaration of Conformity", in which the manufacturer or an authorised representative states that their product complies with the respective applicable legal standards. Depending on the product, the exact requirements for the Declaration of Conformity may vary. In general, however, the document should contain the following:

- Name and address of the manufacturer or their authorised representative
- Serial number, model or type designation of the product
- Declaration of Conformity of the product
- The Assessment Body that carried out the process
- The new British regulations and standards that apply to the product
- Signature with name and date.

Accepted markings on individual UK markets or UK and EU:

Placing products on the market in	Product type	Accepted marking
England, Scotland and Wales	Products to be launched in the UK by the end of 2024	UKCA or CE
England, Scotland and Wales	Products placed on the market in GB on or after 1st January 2025	UKCA
Northern Ireland	Products to be launched in the UK by the end of 2024	CE or CE and UKNI
Northern Ireland	Products placed on the market in GB on or after 1st January 2025	CE or CE and UKNI

Case Study: How FRIWO Implements UKCA Requirements



Since the announcement of the new standard, FRIWO has been working closely with the German Electrical and Electronic Manufacturers' Association (ZVEI) and has prepared a UKCA Declaration of Conformity in good time.

FRIWO was one of the first companies in the German electrical industry to approach the approval authorities and work closely with the ZVEI. Since then, there has been a constructive exchange to understand all requirements in detail and prepare for implementation.

FRIWO's goal is to become a pioneer in marking. The company has already implemented many requirements, even if they're not currently required. This way, the company wants to guarantee its customers and sales partners continuity for business in the UK and seamless implementation of the UKCA requirements.

From 1st January 2025, the UKCA marking must be visible on the device, in accompanying documents or on the folding box. From 1st January 2028 at the latest, the UKCA marking must be present directly on the device.

FRIWO exceeds these requirements and has already started marking its devices. The UKCA marking is applied directly to the devices by laser printing, so various products from the manufacturer already meet the requirements that will apply from 2028. We expect to successfully mark our entire portfolio with the respective markings in the near future.

Checklist: How to Navigate the UKCA Certification Process with Confidence

Before you start the certification process for the UKCA marking, you should first determine whether you've compiled all the necessary information. In the following, FRIWO provides you with the most important information with further sources for the UKCA marking.

☐ **1. Check which rules apply to the products you want to market in England, Scotland or Wales. Since different regulations apply to certain goods, you should first clarify which of your products fall under which regulations.**

- You can find further information here: https://www.gov.uk/guidance/placing-manufactured-goods-on-the-market-in-great-britain#check-which-rules-apply
- Find out here for which product types a self-declaration of conformity is permitted for UKCA marking pursuant to which regulations: https://www.gov.uk/guidance/using-the-ukca-marking#self-declaration
- List of products covered by UKCA marking: https://www.gov.uk/guidance/using-the-ukca-marking#more-information

☐ **2. Make a note of the tasks you must perform during certification. As the manufacturer, you're responsible for ensuring that your product complies with the regulations, and you must compile the documentation for the Declaration of Conformity. As the first importer, you're responsible for ensuring that all products go through appropriate procedures, are marked with the correct information and that the manufacturer's technical documents are available. A copy of the Declaration of Conformity must be kept for 10 years.**

- You can find further information here: https://www.gov.uk/guidance/placing-manufactured-goods-on-the-market-in-great-britain#check-your-legal-responsibilities

☐ **3. FIf necessary, find and designate a "Responsible Person" for the relevant products: the UK only recognises responsible persons or authorised representatives who are based in the UK in the UKCA certification process.**

☐ **4. Make sure you have compiled all documents that are written in English for products that require UKCA certification. Non-English language documents should be translated.**

☐ **5. Find an officially approved Assessment Body based in the UK that can perform product certification for UKCA marking.**

- A list of all UK approved assessment bodies can be found here: https://www.gov.uk/uk-market-conformity-assessment-bodies

FAQs about UKCA

Which products are covered by the UKCA marking?

By and large, the UKCA marking applies to the same products that were covered by the corresponding regulations and directives for CE marking before Brexit. This is because the UK has adopted the regulations almost in their entirety. Please note, however, that the designations of all applicable standards have changed..

What are the deadlines for UKCA marking?

The new marking has been in force since 1st January 2021. However, most products can be exported to and sold in the UK with the CE marking until 31st December 2024. For some product groups such as medical devices, other deadlines apply (as mentioned above).

Can certification for UKCA marking also be issued by an Assessment Body from the EU?

No, since 1st January 2021, certificates for the UK can only be issued by bodies that are based there. Certificates previously issued by Assessment Bodies in the EU have since lost their validity for the marking process.

Does a product with old CE certification that is to be placed on the UK market without modification have to be completely recertified by an EU Assessment Body?

From 1st January 2025, you will in any case need UKCA certification from an officially recognised Assessment Body based in the UK (UK Approved Bodies, UK Notified Bodies). However, since the requirements for the products associated with the certification haven't changed so far, it's often sufficient here to submit those documents that were previously already prepared for the CE certification. All documents should be in English.

What will happen to products with a CE marking exported to the UK by 31st December 2024?

Products with a CE marking that have been exported to England, Wales or Scotland until the end of the transition period on 31st December 2024 and are in a sales warehouse there may still be sold with the CE marking after 1st January 2025.

What information must the technical documentation contain?

According to the UK's government's requirements, the technical documentation must always specify how the product was designed and manufactured, how its conformity with the relevant regulations was achieved, and include the addresses of the manufacturer and all storage facilities. Further specific regulations may apply to the documentation of certain products. Please note that this information may be requested by the UK authorities at any time after certification.

Who has to sign the Declaration of Conformity?

Any company applying for UKCA marking must appoint a person who has the authority to act on behalf of that company and sign the Declaration of Conformity. These requirements are the same as for CE marking, so the same person can sign here.

What does the number under the UKCA marking stand for?

The four-digit number identifies the Assessment Body in the UK that certified the product.

Can the UKCA marking be used together with the CE marking on the same product?

Yes, you can use the UKCA marking and the CE marking in parallel, provided the requirements for both are met. However, they should be clearly separated on the product.

Does the UKNI marking replace the CE marking in Northern Ireland?

No, all products placed on the Northern Irish market will require a CE marking for the foreseeable future. The UKNI marking is only an additional option intended for UK companies and must always be used together with the CE marking.

Do You Have Any Questions or Specific Projects Planned?

It's best to discuss your concerns directly with the respective experts. To shorten the way there as much as possible, you will find an overview of your contact persons here.

Our contact persons for projects in the tools, industrial, medical and e-mobility fields.

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