





# NEW PRODUCT MARKINGS AND CONFORMITY ASSESSMENT

### **Frequently Asked Questions (FAQs)**

### YOU NEED TO ACT NOW

The purpose of this guide is to answer questions on two product marking requirements for businesses placing goods on the UK market.

The UKCA (UK Conformity Assessed) marking is the new product marking required to demonstrate that certain goods are compliant with the UK rules and can be placed on the market in Great Britain (England, Wales and Scotland); it covers goods that previously required the CE marking.

These FAQs do not cover regulations for medical devices, rail interoperability, construction products, civil explosives, and products requiring eco-design and energy labelling on the market. Guidance on these can be found here: medical devices, rail interoperability, construction products, civil explosives, products requiring eco-design and energy labelling)

The UKNI (United Kingdom Northern Ireland) marking is the new conformity marking for products placed on the market in Northern Ireland but only where a UK based conformity assessment body has been used; it also covers goods that continue to require the CE marking. It is used alongside the CE marking for goods which have undergone mandatory third-party conformity assessment by a conformity assessment based in the UK (a UK 'notified body'). Goods with the CE+UKNI marking cannot be sold in the EU. The CE marking is still accepted in Northern Ireland for self-declared and EU Notified Body assessed goods.









#### PART 1: REQUIREMENTS FOR UKCA MARKED PRODUCTS

#### 1. Does my product require the UKCA marking for the GB market?

- Generally, if a product required the CE marking in the past, it will require the UKCA marking for the GB market (England, Wales and Scotland).
- Aerosol containers (which were previously required the reverse epsilon marking) will also be subject to the UKCA marking.
- You can find the UK legislation covering products that require the UKCA marking on our GOV.UK guidance page: 'Placing UKCA and CE marked goods on the UK market':
- For more information and a list of guides on specific product safety and metrology regulations for businesses, see Product safety and metrology from 1 January 2021: Great Britain.

#### 2. Where can I find guidance on the new UK domestic regime and the UKCA requirements?

- Placing UKCA and CE marked goods on the GB market from 1 January 2021 here.
- Using the UKCA marking here.
- Conformity assessment <u>here</u>.
- Placing goods on the market in Northern Ireland <u>here</u>.
- Using the UKNI marking <u>here</u>.
- For guidance on moving goods between NI and GB and vice versa <u>here</u>.

#### 3. What are the timings for the UKCA marking?

#### 1 January 2021

The UKCA marking came into effect on 1 January 2021, so you can already use it on your products. You must use the new UKCA marking before the 1 January 2022 if <u>all</u> of the following apply:

- Your product is for the GB market.
- Your product is covered by legislation which requires the UKCA marking.
- Your product requires mandatory third-party conformity assessment.
- The conformity assessment has been carried out by a UK conformity assessment body.

#### 1 January 2022

It is mandatory to use the UKCA marking in most cases from 1 January 2022 if your product:

- o Is being place on the market in Great Britain; and
- Is covered by legislation which requires the UKCA marking (there are exceptions and alternative guidance for <u>medical devices</u>, <u>rail interoperability</u>, <u>construction products</u>, <u>civil</u> <u>explosives</u>, and <u>products requiring eco-design and energy labelling</u>).

#### • 1 January 2023

- Until 1 January 2023, for <u>most goods</u> you have the option to attach the UKCA marking on a label affixed to the product or on an accompanying document.
- o From 1 January 2023, the UKCA marking must, in most cases, be affixed directly to the product.

#### 4. Applying the UKCA marking on products.

(a). Can I place the UKCA marking on the packaging of the product until my packaging is updated?









- Until 1 January 2023, business have the option to attach the UKCA marking on a label affixed to the product or on an accompanying document.
- Exceptions and specific guidance exist for: <u>medical devices</u>, <u>rail interoperability</u>, <u>construction</u> <u>products</u> and <u>civil explosives</u>, <u>products requiring eco-design and energy labelling</u>).

#### (b). Does the UKCA marking need to be physically on the product itself?

- o The UKCA marking can be applied from 1 January 2021.
- Until 1 January 2023, for most goods currently subject to the CE mark, you have the option to affix the
  UKCA marking on a label affixed to the product or on an accompanying document. The economic
  operators (whether manufacturer, importer, or distributor) should take reasonable steps to ensure
  the UKCA marking remains in place.
- From 1 January 2023, the UKCA marking must, <u>in most cases</u>, be affixed directly to the product. See
   Transitional measures relating to the UKCA marking.
- The manufacturer (or their authorised representative) must affix the UKCA marking visibly, legibly, and indelibly to the product.
- Where rules previously allowed the CE marking to be affixed to packaging or accompanying documents (for example because of the size or nature of the product) the same will apply for the UKCA marking.
- o Check the requirements in the relevant sector specific legislation.

### <u>5. Whose responsibility is it to ensure that products have the UKCA marking? The importer, manufacturer, or distributor?</u>

Responsibility rests with the manufacturer, importer or distributor (the relevant economic operators) at various stages. The UKCA marking is affixed by the manufacturer or their authorised representative.

#### Manufacturer:

 By attaching the UKCA marking, the manufacturer declares that the product conforms to UK legislative requirements including that the required conformity assessments have been completed.

#### Importer:

- When placing goods on the GB market, importers will need to make sure that the goods conform to UK legislative requirements, including that the required conformity assessment procedures have been carried out and that goods have the correct conformity markings.
- Importers must also make sure that the manufacturer has drawn up the correct technical documentation and complied with the labelling requirements. Importers must also label the product with their own name and address.

#### **Distributor:**

 Distributor status carries certain obligations such as taking due care to ensure that the products meet the legislative requirements as well as checking that products are accompanied by the required conformity marking and documentation.

Care must be taken by the relevant economic operator (manufacturer, importer, or distributor) to ensure the product bears the UKCA marking and, in the case of manufacturers, to affix it.









#### 6. Can you define 'Placing on the market'?

A product is placed on the market when there is an offer or an agreement, verbal or written for the transfer of the ownership, possession or any other kind of right, excluding intellectual property rights, concerning the product. It does not therefore require the physical transfer of the product.

- The product is made available for the first time on the market, for distribution, consumption or use during a commercial activity.
- The proof of placing on the market can be contained in contracts of sale, invoice, shipping documents or similar commercial documents.
- See <u>Placing goods on GB market</u>.

### 7. What is the status of 'existing CE stock that has not been placed on the market before 2022 in Great Britain?

- If existing stock is first placed on the market on or after 1 January 2022, it will require the UKCA marking.
- The new GB regulatory requirements only applies to goods placed on the GB market from 1 January 2021. If you had already placed your good on the GB market before 1 January 2021, you do not need to do anything.
- Goods placed on the GB or EU market before this date can continue to circulate on either market until they reach their end user.
- Under the Northern Ireland Protocol, Qualifying Northern Ireland Goods which bear the CE marking can continue to be placed on the GB market.

## PART 2: REQUIREMENTS FOR NORTHERN IRELAND MARKED PRODUCTS

#### **GENERAL APPLICATION OF THE UKNI MARKING**

#### 8. When do I need to apply the UKNI marking to my product?

- From 1 January 2021, you will need to use the UKNI marking if you are placing certain goods on the Northern Ireland market (mostly goods subject to the CE marking and aerosol containers) where the goods:
  - o require mandatory third-party conformity assessment, and
  - o this has been undertaken by a UK notified body.
  - The UKNI marking must accompany the relevant EU conformity mark, usually the CE marking.

#### • Where UKNI marking is inapplicable:

- Applying on its own, it must always accompany the relevant EU conformity mark.
- o If you use an EU notified body, in which case you only apply the relevant EU conformity mark.
- o If your products do not require third-party conformity assessment, apply the CE marking alone. This includes if you self-declare that your products meet EU rules.









#### PLACING GOODS FROM GB TO NI MARKET

#### 9. Will UKCA marked goods be accepted on the NI market without the UKNI marking?

- No, the valid markings for placing goods on the NI market will be the CE marking or the CE + UKNI markings.
- The UKCA marking can appear alongside the CE or the CE + UKNI markings if you are planning on selling your good on the GB and NI market and both sets of relevant rules have been met.
- A product may bear additional markings, if:
  - o they fulfil a different function from that of the CE marking,
  - o are not liable to cause confusion with it, and
  - do not reduce its legibility and visibility.
- Additional marks must not affect the legibility, visibility or meaning of the CE or CE + UKNI marking.
- More information on this can be found <u>here</u>.

#### 10. What is the role of importers and distributors from 1 January 2021 for selling on the NI market?

- The Northern Ireland Protocol came into force on 1 January 2021. The effect of the Protocol is that
  Northern Ireland will align with all relevant EU rules relating to the placing on the market of
  manufactured goods. This means that, where a business already holds the relevant approvals that
  goods meet EU rules, and continues to produce goods to those rules, this continues to provide the
  basis for placing goods on the market in Northern Ireland.
- An importer is the one based in NI (or an EU/EEA county) bringing goods into Northern Ireland from
  either Great Britain or another non-EEA country and placing them on the Northern Ireland market for
  the first time. If those goods have already been placed on the EU or NI market (for example by an EUbased importer, manufacturer or their Authorised Representative) then you do not need to take
  action.
- An importer will need to make sure:
  - o goods conform with the relevant essential requirements.
  - goods are labelled with the details of the importer who must be based in Northern Ireland or the EEA. These details include the company's name, or registered trademark, and a contact address
  - the correct conformity assessment procedures have been carried out and that goods have the correct conformity markings.
  - the manufacturer has drawn up the correct technical documentation and complied with the labelling requirements.
  - o they maintain a copy of the EU Declaration of Conformity for a period of 10 years.

#### PLACING GOODS FROM NI TO GB MARKET

11. Will products marked UKNI be accepted on the rest of the UK market?









- The UK Government has committed to delivering unfettered access for qualifying Northern Ireland goods and businesses to the rest of the UK internal market from 1 January 2021.
- This ensures that trade from Northern Ireland to Great Britain continues for those businesses as it does now.
- This includes accepting qualifying NI goods lawfully bearing a CE or CE+UKNI marking as valid for the rest of the UK market. More information on qualification can be found here.

### 12. Can CE marked products manufactured in NI be placed on the GB market without the application of the UKCA marking?

- The UK Government has guaranteed unfettered access for Northern Ireland goods and businesses to
  the rest of the UK market, which means qualifying NI goods lawfully carrying the CE marking or the CE
  + UKNI markings will be accepted on the GB market (Scotland, Wales, England) without the need for
  additional markings or approvals.
- You can read more about placing qualifying Northern Ireland goods on the GB market here.

### 13. Can I use conformity assessment bodies based anywhere in the UK to certify my product for the NI market?

- Yes. Conformity assessment bodies in the UK automatically retained their status as Notified Bodies for placing products on the NI market only (as per Article 7(3) of the Northern Ireland Protocol).
- UK-based bodies will keep the same 4-digit identification number as they have now.
- UKMCAB lists the UK Notified Bodies who can provide conformity assessment for goods placed on the NI market.
- If an EU assessment body certifies your product, it will carry the CE marking. If you are using a UK
  notified body to carry out mandatory third-party conformity assessment, then you also need to apply
  a UKNI marking (sometimes referred to as the UK(NI) marking or the UK(NI) indication) alongside the
  CE marking.
- You never apply the UKNI marking on its own it always accompanies an EU conformity marking, such as the CE marking. Goods with the CE and UKNI marking cannot be placed on the market in the EU.

#### 14. What are the address requirements for my product when placing on the NI market?

- To place goods on the Northern Ireland market for the first time, an importer will need to be in either Northern Ireland or the EU, or in some cases, in the EEA. This requirement needs to be met when bringing goods from GB into NI. If those goods have already been placed on the EU or NI market (for example by an EU-based importer, manufacturer or their Authorised Representative) then you do not need to take action.
- NI-based manufacturers, distributors and fulfilment service providers (from 16 July 2021) have different responsibilities and you should check the <u>gov.uk guidance</u>.

#### PART 3: EU REQUIREMENTS FOR CE MARKED PRODUCTS

15. What must I do to continue selling my good into the EU/EEA as my current UK-based conformity assessment body cannot provide certification for the CE marking?









- If EU legislation requires mandatory third-party conformity assessment for your product, you will not be able to self-declare compliance and will need to make arrangements to get certification for the EU/EEA.
- Check whether your UK approved body has arrangements in place to help you get certification for the EU market. This may mean you can export to the EU without needing to find a new EU notified body yourself.
- If not, you need to either:
  - o get your products assessed by an EU recognised notified body; or
  - arrange for information held by your existing UK approved body to be transferred to an EU recognised notified body so they can issue you with an additional certificate.
- EU notified bodies continue to be listed on NANDO.

#### 16. Do my goods need to be labelled with my importer's name and address?

- Where there is an EU importer, the importer needs to make sure goods are labelled with their details (or the importer's authorised representative) who must be based in Northern Ireland, the EU, or the
- These details include the company's name, or registered trade mark, and a contact address.
- From 16 July 2021, you will need to make sure that there is an economic operator based in the EU or
  NI to be able to undertake certain task, which may mean you need to appoint an authorised
  representative based in the EU or EEA if you sell goods without using an importer or fulfilment service
  provider. For example, if you sell online and ship directly to the end user.

#### 17. Do I need to appoint an Authorised Representative to sell my goods in the EU?

- Manufacturers can appoint Authorised Representatives (ARs) to carry out tasks on their behalf.
- Generally, the appointment of an authorised representative is optional for CE marked goods, but you
  will need to check the specific <u>legislation</u> that applies to your product to confirm whether you are
  required to appoint an AR, as for some goods it will be compulsory to have an economic operator
  based in the EU (or NI) from 16 July 2021; from this date "economic operator" includes fulfilment
  service providers, as well as manufacturers, their authorised representatives, importers and
  distributors, if there is no other economic operator based in the EU or NI, you may need to appoint an
  AR.
- It is mandatory for some products in cases where the manufacturer is not based in an EU country, for example medical devices.
- In all cases, whether compulsory or voluntary, ARs based in Great Britain are no longer recognised by the EU. If you are required to by the relevant EU legislation, you will need to appoint an AR based in the EU, EEA, or Northern Ireland.

#### 18. Can I place the CE marking on my good as well as the UKCA marking?

 Yes, you can place the UKCA and CE marking on the same product if it is destined for both markets so long as the product meets the relevant regulatory requirements for both markets. You can find EU legislation <u>here</u>. Relevant UK legislation can be found <u>here</u>.









- A product may bear additional markings if they:
  - o fulfil a different function,
  - o are not liable to cause confusion with it, and
  - o do not reduce its legibility, visibility or meaning.

### **Part 4: Conformity Assessment**

#### 19. Who can sign a Declaration of Conformity?

- As a manufacturer, it is your responsibility to sign the Declaration of Conformity.
- Depending on the conformity assessment procedure and the relevant legislation, an authorised representative may be permitted to draw up and sign the declaration of conformity.

#### 20. Where can I find a UK Approved Body (formerly Notified Body) for my good?

- From 1 January 2021 UK-based notified bodies (NBs) automatically became UK approved bodies.
- UK approved bodies are listed on the UK Market Conformity Assessment database (UKMCAB).
   www.gov.uk/uk-market-conformity-assessment-bodies.

#### 21. Can I self-declare my good?

- If before the end of the transition period EU legislation allowed for self-assessment of conformity for the CE marking, the law allows self-declaration for the UKCA marking.
- If that is the case, the manufacturer can affix the UKCA marking and draw up the UK Declaration of Conformity.
- This can be done even when they are not based in the UK. <a href="https://www.gov.uk/guidance/using-the-ukca-marking#self-declaration">https://www.gov.uk/guidance/using-the-ukca-marking#self-declaration</a>

### 22. What are the requirements for a Declaration of Conformity for a product manufactured in Northern Ireland?

- Where third party conformity assessment is required, manufacturers will be able to have a certificate of conformity issued by a UK-Notified Body that will enable them to apply the CE and UKNI marking (together) or an EU based notified body that will enable them to apply the CE marking.
- If you are a manufacturer based in Northern Ireland (or are the manufacturer's authorised representative), and you currently mark your goods based on a supplier's declaration of conformity, sometimes known as 'self-certifying' or self-declaring, you may continue as before the UK left the EU on 31 December 2020.
- Your EU Declaration of Conformity should contain the following information:
  - Your name and full business address or that of your authorised representative (authorised representative must be based in the NI or the EU for goods placed on the market in NI).
  - o The product's serial number/model/type identification.
  - A statement, stating you take full responsibility (to be completed once the products have positive conformity assessment).
  - o For some products you are required to include a product description/image.









- The details of the conformity assessment body which will be carrying out the conformity assessment procedure (refer to step 2 for appropriate conformity assessment body for your chosen market).
- The relevant EU legislation.
- o If applicable list the Harmonised Standards or other means used to prove compliance.
- Your name and signature.
- The date the declaration was issued.
- Supplementary information (if applicable).
- The EU Declaration of Conformity must be available to market surveillance authorities upon request.
- For products that are placed on the NI market from any country outside the EU/EEA, the NI or EU-based importer must retain a copy of the EU Declaration of Conformity. This includes products brought into NI from Great Britain, as Great Britain is treated as third country under the relevant EU legislation that applies in NI. The manufacturer or their authorised representative (where applicable) must also retain a copy of the EU Declaration of Conformity.

#### **PART 5: IMPORTER OBLIGATIONS**

#### 23. Is there a grace period for attaching the importer's name and address to the good in the UK?

- Yes, until <u>31 December 2022</u>, you can provide these details on the accompanying documentation rather than on the good itself when they are coming from the EEA, or Switzerland
- Different rules apply for <u>medical devices</u>, <u>rail interoperability</u>, <u>construction products</u> and <u>civil</u> explosives, products requiring eco-design and energy labelling.

#### 24. Does an importer need to be a UK based entity?

- To place goods on the GB market, the importer needs to be based in the UK this includes Northern Ireland
- To place goods on the NI market, the importer and the manufacturer's authorised representative need to be based in NI, the EU, or the EEA.
- For goods placed on the GB market, the importer is the first UK-based entity to place a product on the GB market from outside the UK (this includes a business based in NI who places a product on the GB market which has been supplied to them from an EU country).

ANNEX A









Manufacturer	The manufacturer is anyone who manufactures a product or has a product designed
	or manufactured and markets that product under its name or trademark.
Importer	The importer is a person who is established in the relevant market and is the first
	to place goods from an external market onto the market that they operate in.
Distributor	The distributor is a person, other than the manufacturer or the importer, who
	makes goods available on the market.
Authorised	An "authorised representative" means a person or business appointed and
representative	mandated by the manufacturer to undertake specified tasks on behalf of the
	manufacturer. There are rules as to where an authorised representative (AR) must
	be established – for the GB market the manufacturer's AR must be established in
	the UK; for the NI market and AR must be established in NI or the EU/EEA.
	the ox, for the Williamset and Altitude be established in Wild the EdyLea.
Fulfilment service	A "fulfilment service provider" is legally defined by Regulation (EU) 2019/1020
provider	(which will apply in NI and the EEA from 16 July 2021), as follows "any natural or
provide:	legal person (business) offering, in the course of commercial activity, at least two of
	the following services: warehousing, packaging, addressing and dispatching, without
	having ownership of the products involved, excluding postal services as defined in
	point 1 of Article 2 of Directive 97/67/EC of the European Parliament and of the
	Council (31), parcel delivery services as defined in point 2 of Article 2 of Regulation
	(EU) 2018/644 of the European Parliament and of the Council (32), and any other
	postal services or freight transport services"; as yet there is no legal definition of
	"fulfilment service provider" for the purposes of GB product safety legislation.



