

Market Changes between the UK and EU from 1st January 2021

This document presents an overview of changes to the way goods can be placed on the UK market from the EU and on the EU market from the UK. This follows the implementation of the Brexit process.

It is important to recognise that this is a fluid situation, ongoing negotiations over trade deals may impact transfer of goods further and the guidance in this document may become out of date.

This document covers three primary areas:

- Placing manufactured goods on the market in Great Britain from 1st January 2021
- Placing manufactured goods on the EU market from 1st January 2021
- Using the UKCA mark from 1st January 2021

1. Placing manufactured goods on the market in Great Britain from 1st January 2021

(Source: <https://www.gov.uk/guidance/placing-manufactured-goods-on-the-market-in-great-britain-from-1-january-2021>)

This guidance is about placing manufactured goods on the market in Great Britain (GB). Great Britain is England, Wales and Scotland.

There's different guidance if you're:

- placing manufactured goods on the EU market
- placing manufactured goods on the market in Northern Ireland from Great Britain
- placing manufactured goods on the market in Northern Ireland from the EU

If you have already placed your goods on the UK market (or in an EU country) before 1st January 2021, you do not need to do anything.

Businesses are encouraged to be ready for full implementation of the new UK regime as soon as possible after 1st January 2021. However, to allow businesses time to adjust, CE marked goods in scope of this guidance that meet EU requirements (where these match UK requirements) can continue to be placed on the GB market until 1st January 2022 where EU and UK requirements remain the same. This includes goods which have been assessed by an EU recognised notified body. There are some exceptions to this guidance, highlighted below.

What you will need to do from 1 January 2021 depends on the type of goods you are placing on the market. There are different rules for:

- new approach goods
- goods regulated under the old approach
- goods covered by national rules (non-harmonised)
- certain other goods, such as medical devices and civil explosives

Most of this guidance covers goods often known as new approach goods.

You must follow different rules if you are placing old approach goods on the UK market. The following goods are covered by the old approach:

- chemicals
- medicines
- vehicles

- aerospace

For goods covered by national rules (non-harmonised) you must make sure that your goods meet UK rules. You will need to do this even if they were previously sold in an EU country.

Other goods. There are also special rules if you're placing the following goods on the UK market:

- medical devices
- rail interoperability
- construction products
- civil explosives

New approach goods.

Placing certain goods on the UK market requires use of a conformity mark:

- Before 1st January 2021 you can do this using the CE or other appropriate mark
- From 1st January 2021, the UKCA mark will be the conformity assessment marking for Great Britain for most goods currently subject to CE marking.
- The CE mark will be accepted in the UK until 1 January 2022 for certain products, but you must be ready to use the UKCA marking from 1 January 2022 at the latest.
- You will need to use the new UKCA marking immediately after 1st January 2021 if all the following apply. Your product:
 - is covered by legislation which requires the UKCA marking
 - requires mandatory third-party conformity assessment
 - conformity assessment has been carried out by a UK conformity assessment body and you haven't transferred your conformity assessment files from your UK body to an EU recognised body before 1st January 2021. This does not apply to existing stock, for example if your good was fully manufactured and ready to place on the market before 1 January 2021.

You will be able to use the CE marking until 31 December 2021 if any of the following apply:

- you currently apply the CE marking to your goods on the basis of self-declaration
- any mandatory third-party conformity assessment was carried out by an EU-recognised notified body
- the certificate of conformity previously held by a UK approved body has been transferred to an EU-recognised notified body

CE marked goods that meet EU requirements can only be placed in Great Britain while UK and EU requirements are the same. This will be the case on 1st January 2021 and there are no UK plans to diverge at this time. If the EU changes their rules and goods are CE marked based on new EU rules, you will no longer be able to use the CE marking in the UK if the new rules differ from UK requirements. This will be the case even if the change happens before 1st January 2022.

CE marking for both the GB and EU market

UKCA marking will not be recognised on the EU or Northern Ireland markets. Products currently requiring a CE marking for sale in the EU will continue to need a CE mark.

You will not need to take any action from 1st January 2021 if either of the following apply:

- you self-declare the conformity of your good against the regulations

- you voluntarily use a testing or notified body to test against European or international standards

You may need to take additional action if your good needs third-party conformity assessment.

Goods can carry both the CE and UKCA markings so long as they are fully compliant with both UK and EU regulations.

Manufacturers

Your legal obligations will remain largely unchanged from 1st January 2021.

UK distributors and suppliers

You will need to confirm whether you or your supplier will become an 'importer' after 1st January 2021. You will become an importer if you are the one bringing goods into the UK from outside the UK and placing them on the market in Great Britain.

You will need to make sure:

- goods are labelled with your company's details, including your company's name and a contact address (until 31st December 2022 you can provide these details on the accompanying documentation rather than on the good itself)
- 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 their labelling requirements
- you maintain a copy of the declaration of conformity for a period of 10 years
- goods conform with the relevant essential requirements

Existing stock

Existing stock that has been fully manufactured and conformity marked can still be placed on the GB market after 1st January 2021 with existing markings and notified body numbers. So, goods can still be sold in the UK with a CE marking so long as they are from pre-existing stock fully manufactured before 31st December 2020.

2. Placing manufactured goods on the EU market from 1st January 2021

This guidance is about placing manufactured goods on the EU market.

There's different guidance if you are:

- placing manufactured goods on the market in Great Britain
- placing manufactured goods on the market in Northern Ireland from Great Britain
- placing manufactured goods on the market in Northern Ireland from the EU

If you have already placed your goods on the market in an EU country (or in the UK) before 1st January 2021, you do not need to do anything.

What you will need to do from 1st January 2021 depends on the type of goods you are placing on the market. There are different rules for:

- new approach goods
- goods regulated under the old approach (such as chemicals, medicines, and vehicles)
- goods covered by national rules (non-harmonised)
- certain other goods, such as medical devices and civil explosives

Most of this page covers goods known in the EU as new approach goods, which can use the CE marking. There are different rules for:

- goods regulated under the old approach
- non-harmonised goods covered by national legislation

You must follow special rules if you are placing old approach goods on the EU market.

For non-harmonised goods, you must make sure that your goods meet the requirements of the first EU or EEA country in which you are placing them on the market.

Conformity assessment

You will not need to change your conformity assessment for exports to the EU if:

- you self-declare the conformity of your good against the regulations
- any mandatory third-party conformity assessment was carried out by an EU-recognised notified body (whether based in the EU or in a country with which the EU has a mutual recognition agreement)
- the certificate of conformity previously held by a UK body has been transferred to an EU-recognised notified body
- you voluntarily use a testing body (including UK bodies) to test against European or international standards

UK conformity assessment

From 1st January 2021 any mandatory conformity assessment will need to be carried out by an EU-recognised conformity assessment body. This includes both EU based bodies and bodies in countries with which the EU has concluded a mutual recognition agreement.

UK conformity assessment bodies will no longer be able to carry out mandatory conformity assessment for products being placed on the EU market unless agreed in negotiations.

Your UK notified body should be taking steps to ensure that you can continue to export to the EU without needing to find a new EU notified body.

If not, you will need to either:

- get your products reassessed by an EU notified body
- arrange for information held by your existing notified body to be transferred to an EU notified body so they can issue you a new certificate

Certificates and documentation

If you transfer your existing certificate to an EU notified body, then you will need to update the 4-digit notified body number on your products. You will not need to do this for products already on the market or which were manufactured before the transfer took place.

You will eventually need separate certificates for the UK and EU so that you will be covered for both markets in the future. If you transfer your certificate to the EU without doing this, you may not be able to continue selling your goods in the UK from 1st January 2022 without having your product reassessed.

EU and UK notified bodies are required to share information when requested by a certificate holder. This will help facilitate the issuing of new certificates of conformity where needed.

Appoint an authorised or responsible person

Authorised representatives and responsible persons based in Great Britain will no longer be recognised by the EU from 1st January 2021.

If you're required to, you will need to appoint an authorised representative or responsible person based in the EU, EEA or Northern Ireland.

From 16th July 2021 you will 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.

Manufacturers

Your legal obligations will remain largely unchanged from 1st January 2021.

EU-based distributors

If you have an EU based distributor, they will become an 'importer' from 1st January 2021. They will need to ensure:

- goods are labelled with their address and either your details or your EU, EEA, or Northern Ireland-based authorised representative's details (including your company's name and a contact address or registered trademark)
- the correct conformity assessment procedures have been carried out and that goods have the correct conformity markings
- you, as the manufacturer, have drawn up the correct technical documentation and complied with the labelling requirements
- they maintain a copy of the declaration of conformity for a period of 10 years
- goods conform with the relevant essential requirements

EU-based fulfilment service providers

From 16th July 2021, if you use an EU-based fulfilment service provider, they will need to request certain compliance information from you, and goods will need to be labelled with their details. They may ask that you appoint an authorised representative who can fulfil these obligations instead.

3. Using the UKCA mark from 1st January 2021

The UKCA (UK Conformity Assessed) marking is a new UK product marking that will be used for goods being placed on the market in Great Britain (England, Wales, and Scotland). It covers most goods which previously required the CE marking.

The UKCA marking alone cannot be used for goods placed on the Northern Ireland market, which require the CE marking or UK(NI) marking.

You will need to use the new UKCA marking immediately after 1st January 2021 if all the following apply. Your product:

- is for the market in Great Britain
- is covered by legislation which requires the UKCA marking
- requires mandatory third-party conformity assessment
- conformity assessment has been carried out by a UK conformity assessment body and you haven't transferred your conformity assessment files from your UK body to an EU recognised body before 1st January 2021

This does not apply to existing stock, for example if your good was fully manufactured and ready to place on the market before 1st January 2021. In these cases, your good can still be

sold in Great Britain with a CE marking even if covered by a certificate of conformity issued by a UK body.

Selling goods in Great Britain

The UKCA marking will apply to most goods currently subject to the CE marking.

From 1st January 2021 the technical requirements ('essential requirements') you must meet (and the conformity assessment processes and standards that can be used to demonstrate conformity) will be largely the same as they are now.

The UKCA marking can be used from 1st January 2021. However, to allow businesses time to adjust to the new requirements, you will still be able to use the CE marking until 1st January 2022 in most cases. In some cases, you will need to apply the new UKCA marking to goods being sold in Great Britain immediately from 1st January 2021.

The CE marking will only be valid in Great Britain for areas where GB and EU rules remain the same. If the EU changes its rules and you CE mark your product based on those new rules you will not be able to use the CE marking to sell in Great Britain even before 31st December 2021.

There is separate guidance for medical devices, rail interoperability, construction products and civil explosives.

Selling goods in the EU

The UKCA marking will not be recognised on the EU market. Products currently requiring a CE marking will still need a CE marking for sale in the EU from 1st January 2021.

Placing the UKCA marking

In most cases, you must apply the UKCA marking to the product itself or to the packaging. In some cases, it may be placed on the manuals or on other supporting literature. This will vary depending on the specific regulations that apply to the product.

The following general rules apply:

- UKCA markings must only be placed on a product by you as the manufacturer or your authorised representative (where allowed for in the relevant legislation)
- when attaching the UKCA marking, you take full responsibility for your product's conformity with the requirements of the relevant legislation
- you must only use the UKCA marking to show product conformity with the relevant UK legislation
- you must not place any marking or sign that may misconstrue the meaning or form of the UKCA marking to third parties
- you must not attach other markings on the product which affect the visibility, legibility or meaning of the UKCA marking
- the UKCA marking cannot be placed on products unless there is a specific requirement to do so in the legislation

Rules for using the UKCA image



You must make sure that:

- if you reduce or enlarge the size of your marking, the letters forming the UKCA marking must remain in proportion to the standard mark

- the UKCA marking is at least 5mm in height – unless a different minimum dimension is specified in the relevant legislation
- the UKCA marking is easily visible, legible (from 1st January 2023 it must be permanently attached)

Record keeping

You, or your authorised representative, must keep documentation to demonstrate that your product conforms with the regulatory requirements. This must be kept for up to 10 years after the product is placed on the market. This information can be requested at any time by market surveillance or enforcement authorities to check that your product conforms with the statutory requirements.

The information you must keep will vary depending on the specific legislation relevant to your product. You must keep general records of:

- how the product is designed and manufactured
- how the product has been shown to conform to the relevant requirements
- the addresses of the manufacturer and any storage facilities

You should keep the information in the form of a technical file which can be supplied if requested by a market surveillance authority.

UK Declaration of Conformity

The UK Declaration of Conformity is a document which must be drawn up for most products lawfully bearing a UKCA marking. In the document you as the manufacturer, or your authorised representative should:

- declare that the product is in conformity with the relevant statutory requirements applicable to the specific product
- make sure the document has the name and address of the manufacturer (or your authorised representative) together with information about the product and the conformity assessment body (where relevant)

The information required on the Declaration of Conformity will be largely the same as what is currently required on an EU Declaration of Conformity. This can vary depending on the application legislation but generally should include:

- your name and full business address or that of your authorised representative
- the product's serial number, model, or type identification
- a statement, stating you take full responsibility for the product's compliance
- the details of the approved body which carried out the conformity assessment procedure (if applicable)
- the relevant legislation with which the product complies
- your name and signature
- the date the declaration was issued
- supplementary information (if applicable)

You will need to list:

- relevant UK rather than EU legislation
- UK designated standards rather than standards cited in the Official Journal of the European Union

On 1st January 2021, the UK standards will be the same in substance and with the same reference as the standards used in the EU. However, they will use the prefix 'BS' to indicate that they are standards adopted by the British Standards Institution as the UK's national standards body.

Future use of markings in the UK

From 1st January 2022, the CE marking will not be recognised in Great Britain for areas covered by this guidance and the UKCA marking. However, a product bearing the CE marking would still be valid for sale in the UK so long as it was also UKCA marked and complied with the relevant UK rules.

Product areas covered by the UKCA marking include:

- Simple pressure vessels
- ATEX
- Pressure equipment
- Machinery
- Restriction of hazardous substances

There are also products covered by the UKCA marking but having some special rules:

Transitional measures relating to the UKCA marking

For many product types of the following transitional measures apply.

Until 1st January 2023, for most goods (other than those subject to special rules) you have the option to affix the UKCA marking on a label affixed to the product or on an accompanying document. Products that require the UKCA marking cannot be made available without it (other than where the CE marking is being used before 1st January 2022).

From 1st January 2023, the UKCA marking must, in most cases, be affixed directly to the product. You should start building this into your design process ready for this date.