

NSAI



Rialtas na hÉireann
Government of Ireland

FAQs for Product Certification

Are you ready? **1.1.21**



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Brexit's impact on product certification

The United Kingdom (UK) left the European Union (EU) on 31 March 2020. The EU-UK Trade and Cooperation Agreement (TCA) came into effect when the Transition Period ended at 11pm on 31 December 2020 and trade between the EU (including Ireland) and the UK has been on the basis of the TCA since then.

The Trade and Cooperation Agreement:

- Provides for tariff and quota free goods trade.
- Protects the Single Market that is so important for Ireland's future prosperity and ensures fair competition for Irish businesses.
- It **does not** replicate the status quo ante. The UK's decision to leave the EU means that the EU-UK relationship cannot be as close as it was when they were members of the EU.
- This means that it remains absolutely vital for businesses and citizens to prepare for the changes that came on 1 January 2021, especially regarding checks and controls for goods moving from, to or through Great Britain.
- **The seamless trade existed up to 31 December 2020 has ended.**
- The EU and UK now have an agreed approach on all issues relating the Protocol on Ireland/Northern Ireland, with close cooperation on the full and effective implementation of the Protocol

Impact on product certification

Brexit has meant changes in the application of regulation or standards when placing goods on the EU market.

These include:

- UK certification bodies cannot be used to certify products for the EU market.
- UKAS accredited test certificates are not recognised where 'accreditation' within the meaning of Regulation No 765/2008 applies.
- Authorised representatives cannot be based in Great Britain (England, Scotland or Wales).

But some things have not changed. EU law still applies to all products placed on the EU market, including those from the UK. The rules that apply are those where the product is placed on the market, not where it is manufactured.

This includes:

- CE marking if required by EU product legislation,
- Certification by an EU notified body if required by EU product legislation,
- Having a valid and up to date EU Declaration of Conformity.

The Protocol on Ireland/Northern Ireland means that EU product legislation continues to apply in Northern Ireland, and it is treated as if it is part of the EU Single Market.

Frequently Asked Questions

Question 1.

How does Brexit impact trade with Northern Ireland?

The Protocol on Ireland/Northern Ireland ('the Protocol') ensures that no hard border on the island of Ireland and protects Ireland's place in the EU Single Market and Customs Union.

Under the Protocol, EU product legislation continues to apply in Northern Ireland from 1 January 2021. Northern Ireland continues to be treated as if it is part of the EU Single Market and Customs Union.

This means that goods moving between Northern Ireland and the EU can continue to do so with no significant changes and the responsibilities of economic operators in the EU generally remain the same as if they are trading within the EU Single Market.

Question 2.

I am based in Ireland, and export products to the UK - how does Brexit impact this?

On 1 January 2021 the UK replaced product certification related EU legislation with UK legislation. All products placed on the UK market have to comply with applicable UK legislation. As an Irish exporter to the UK, you should get familiar with the UK legislation that applies to your products.

This applies to products placed on the Great Britain market, that is England, Scotland and Wales. Because of the Protocol on Ireland/Northern Ireland, it does not apply to the Northern Ireland market.

UK temporary recognition of CE marking

UK product legislation has applied since 1 January 2021, it includes a transition period up to 31 December 2021 during which CE marked products can still be placed on the Great Britain market.

They must have a valid EU Declaration of Conformity, and be certified by an EU notified body to EU harmonised standards where required by EU law.

There is longer transition period for medical devices medical devices of 2.5 years which means CE marked medical devices will be accepted in Great Britain up to 30 June 2023.

Once this period ends CE marked products will no longer be accepted for the Great Britain market.

Customs

The UK left the EU Customs Union on 31 December 2020. Since then, the UK is treated the same as other third countries. Goods exported to Great Britain require an export declaration (including a Safety and Security declaration), are be subject to customs control and may require a licence under prohibitions and restrictions rules.

Irish business exporting to Great Britain are required to have an Economic Operator Registration and Identification (EORI) number, which you can register for on the Revenue Commissioners website.

Question 3.

I import products from the UK - how does Brexit impact this?

EU product legislation applies to all products placed on the EU market from the UK. This means that all products must meet the essential requirements set out in EU legislation, be CE marked if required by EU product legislation, certified by an EU notified body if required by EU product legislation and have a valid and up to date EU Declaration of Performance.

Products from UK manufacturers can continue to be placed on the EU (Irish) market once they are certified by an EU notified body and are CE marked. You should contact your UK suppliers and ask if they will continue to CE mark their products after 1 January 2021.

Economic Operators

Since 1 January 2021 any business importing products from Great Britain has become an importer, as they are the individual who first places a product from a third country on the EU market. By becoming an importer, you have taken on the additional responsibilities as set out in the European legislation.

You should:

- Find out the additional responsibilities you will be taking on
- Engage with the manufacturers of the products
- Ensure that you can get the information and assurances you need
- Be able to access the technical file if required by market surveillance authorities
- Your details are to be included in packaging and product information leaflets.

Customs

Since 1 January 2021 the UK is no longer part of the EU Customs Union. All goods imported from Great Britain now:

- Require an import declaration
- May need an import Safety and Security declaration
- Are subject to customs control
- May require a licence under prohibitions and restrictions rules
- May incur Value-Added Tax (VAT), Excise Duty and Customs Duties.

Since 1 January 2021 Irish business importing from Great Britain are required to have an Economic Operator Registration and Identification (EORI) number, which you can register for on the Revenue Commissioners website.

Question 4.

I import 'CE' marked product that is manufactured in the UK. Is the UK manufacturer required to use a conformity assessment body based in the EU before they can place the product on the EU market?

Where EU product legislation requires conformity assessment by a notified body UK manufacturers are required to have this completed by either a notified body that is based in either the EU or a country with which the EU has a mutual recognition agreement covering the relevant sector.

This is not changed by Brexit. However, on 1 January 2021 UK notified bodies ceased to be EU notified bodies and any manufacturer who used a UK notified body must have their products certified by a notified body based in an EU country. There is more information in Questions 9-12 below.

Question 5.

How and when must my product's EU Declaration of Conformity be made available?

The EU's 'Blue Guide' on the implementation on of EU product rules explains that: 'The EU Declaration of Conformity must be made available to the surveillance authority upon request. Moreover, Union harmonisation legislation relating to machinery, equipment in potentially explosive atmospheres, radio and terminal telecommunication equipment, measuring instruments, recreational craft, lifts, high-speed and conventional rail systems and constituents of the European Air Traffic Management network require products to be accompanied by the EU Declaration of Conformity.'

For further particulars on requirements for declarations of conformity you should consult the 'Blue Guide' and the applicable market surveillance authority(s). There are a number of market surveillance authorities in Ireland, each with their own competencies. Details of the Irish market surveillance authorities along with their responsibilities under EU product safety legislation are available on the NSAI website.

NSAI is a market surveillance authority in the area of measuring instruments, non-automatic weighing instruments, pre-packaged products and units of measurement. This is carried out through our Legal Metrology Service (LMS).

Question 6.***Does my product need to be CE marked post-Brexit?***

There were no changes to EU product legislation because of Brexit and any products which were required to be CE marked before the end of the transition period on 31 December 2020 still need to meet the same requirements today.

CE marking is only obligatory for products for which EU specifications exist and require the affixing of CE marking. You must make sure that your product complies with all the relevant requirements before affixing the CE marking to it. It is forbidden to affix the CE marking to products for which EU specifications do not exist or do not require the affixing of CE marking. In order to apply a CE mark to a product, it must be tested and found to be in compliance with the relevant EU legislation, which can be found on the EU Commission's website.

The Official Journal of the European Union contains a full list of the EU's Directives and Regulations. You can find more information on CE marking on the EU Commission website.

Question 7.***Where can I get my products CE marked? Is this affected by Brexit?***

Under EU product legislation manufacturers bear sole responsibility for declaring conformity with all requirements.

Self-declaration is not affected by Brexit. If the CE marking is based on self-declaration by the manufacturer this will still be possible for UK manufacturers to use self-declaration when CE marking their products for export to the EU. You don't need a license to affix the CE marking to your product, however, before doing so, you must fulfil certain steps. These are outlined in the relevant EU product legislation.

However, some products are required by the EU to be independently assessed by a 'notified body'. Products which are required by the EU to be independently assessed by an EU notified body, will still require independent this independent assessment by an EU notified body post-Brexit. You need to check if your product has to be tested by a notified body. You can find this information in the legislation that applies to your product.

The details of all EU notified bodies are available on the EU NANDO database. You can search this website for a notified body that can certify your product. UK-based conformity assessment bodies ceased to be EU notified bodies on 31 December 2020 and cannot be used when CE marking your products for the EU market.

Question 8.

I use a UK-based notified body for product certification to access the EU market. Will Brexit impact this?

Since 1 January 2021, UK-based notified bodies are no longer EU notified bodies and you cannot use UK notified bodies for product certification to access the EU market. You must find another notified body based in an EU Member State to CE certify your product. The details of all EU notified bodies are available on the EU NANDO database.

Question 9.

The UK notified body I use has established a partner in another EU country. Will my certification still be valid?

On 1 January 2021 all notified bodies in the UK ceased to be recognised as EU notified bodies and you cannot use UK-based notified bodies for product certification to access the EU market.

If you used a notified body which is based in the UK for CE marking purposes, but it established itself in another EU Member State, you should have arranged the transfer of your certification from the UK based notified body to the new notified body before 31 December 2020. You need to update your Declaration of Conformity to include the new notified body's details and ensure that the number of the new notified body accompanies the CE mark on your products.

If you did not transfer your certification before 31 December 2020 you will need to complete the full conformity assessment process with the new notified body.

Certification from the UK based notified body is no longer acceptable for CE marking purposes since 1 January 2021.

Question 10.

The certificate for my product transferred from a UK notified body to an EU 27 notified body. Do the EU Declaration of Conformity and the notified body number and contact details need to be updated to document this change?

Yes, for products placed on the EU market since the 1 January 2021, both the EU Declaration of Conformity (drawn up by the manufacturer) and the notified body number and contact details must be updated accordingly. Both of these documents will have to state that the certificate is now under the responsibility of an EU notified body and indicate both the old UK and the new EU notified body's details/identification numbers.

Question 11.

Does the notified body number on the product itself need to be changed also for products already on the market or manufactured before the transfer of the certificates occurred?





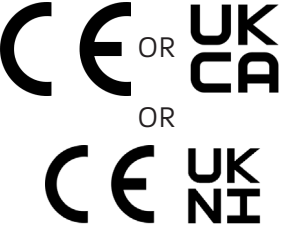

If the product documentation is in order, as set out in answer to question [11], there is no need to change the notified body number for products already placed on the EU market before the end of the transition period on 31 December 2020, even if they are not sold on to the final customer until 2021.

However, products manufactured after the transfer of the certificate has taken place should be marked with the new EU notified body number.

Question 12.

What is the difference between CE marking, UKNI and UKCA markings and which one should I use?

Your goods may require different markings for different markets. The table below illustrates the accepted markings on each market.

	Type of good (See list of product areas below)	Accepted markings of combination of markings
Placing products on the market in Northern Ireland (NI)	Manufactured products being placed on the NI market using an EU conformity assessment body	
	Manufactured products being placed on the NI market using a UK-based body	
Placing products on the market in Great Britain (GB)	Manufactured products being placed on the GB market until the end of 2021	
	Manufactured products placed on the GB market from 1 January 2022	
Placing qualifying Northern Ireland (NI) products on the market in Great Britain (GB) (unfettered access)	Qualifying NI products being placed on the GB market under unfettered access	
Placing products on the EU market	Manufactured products being placed on the EU market	

- For more on UKNI marking see the UK Government website: [gov.uk/guidance/using-the-ukni-marking#overview](https://www.gov.uk/guidance/using-the-ukni-marking#overview)
- For more on UKCA marking see the UK Government website: [gov.uk/guidance/using-the-ukca-marking#how-to-use-the-ukca-marking](https://www.gov.uk/guidance/using-the-ukca-marking#how-to-use-the-ukca-marking)
- For more on CE marking see the EU Commission website: [europa.eu/youreurope/business/product-requirements/labels-markings/ce-marking/index_en.htm](https://europe.europa.eu/business/product-requirements/labels-markings/ce-marking/index_en.htm)

Question 13.

Can my product have more than one marking on it?

You may use combinations of the product markings listed in table in Question 13 and your products may be acceptable with more than one marking. Your products will need to meet the essential requirements of the EU and UK legislation covering the markings you use, i.e. to use the CE mark your products must comply with EU product legislation and if you use the UKCA mark on the same product it must also comply with UK product legislation.

Any products bearing the CE mark do not need to be marked with CE UK(NI) mark as the CE mark will be recognised for all circumstances where the CE UK(NI) mark could be used.

Question 14.

I import a CE marked product that is manufactured in the UK. A transaction of sale between my company and the UK company took place before 31 December 2020 but the physical delivery of the product will not take place until after that date. Can I still place this product on the EU market?

The important cut off point is whether a specific product was placed on the EU market before 11pm on 31 December 2020. The date of placing on the EU market has been defined as the date of the transaction between the UK economic operator (manufacturer, importer or distributor) and the EU (i.e. Irish) customer. Placing on the market does not require physical delivery of the product. However, it does require the product to have left the manufacturers property.

The date of placing on the EU market can be demonstrated using any relevant document ordinarily used in business transactions (e.g. contract of sale concerning goods which have already been manufactured, invoice, documents concerning the shipping of goods to distribution or similar commercial documents). Proof may need to be given in case of checks upon importation into the EU (Ireland) or in case of checks by EU market surveillance authorities.

There is guidance available in the EU Commission notice to stakeholders on industrial products.

Further Information

- For general information on Brexit readiness in the area of standards and certification post-Brexit, see the NSAI website (nsai.ie/Brexit)
- Any queries or questions related to standards and certification post-Brexit can be directed to BrexitUnit@nsai.ie
- The Department of Enterprise, Trade and Employment has a Brexit Readiness Checklist which highlights key actions that businesses can take to get ready for the changes Brexit caused on 1 January 2021. The checklist includes links to the relevant Agencies who can provide the necessary guidance and support to businesses. The checklist is available on the Department website (enterprise.gov.ie/en/What-We-Do/Supports-for-SMEs/Brexit-Supports/#checklist).
- The EU Commission sector specific guidance notices to stakeholders on the withdrawal of the UK and EU rules are available on their website (ec.europa.eu/info/relations-united-kingdom/overview/consequences-public-administrations-businesses-and-citizens-eu_en).
- The European Union's Blue Guide on the implementation of product safety rules provides detailed guidance on economic operators such as distributors and the definition of placing on the market. It is available to download on the EU Commission website ([eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016XC0726\(02\)&from=BG](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016XC0726(02)&from=BG)).
- For UK Government information concerning the UK market see the UK Government website (gov.uk/transition).

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