NSAI

Rialtas na hÉireann
Government of Ireland

FAQs for Product Certification

The EU-UK Trade & Cooperation Agreement

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Brexit's Impact on Product Certification

The United Kingdom (UK) left the European Union (EU) on 31 January 2020 after both sides concluded the Withdrawal Agreement. The Withdrawal Agreement provided for a transition period, which ended on 31 December 2020. The EU-UK Trade and Cooperation Agreement (TCA) came into effect when the transition period ended at 11pm on 31 December 2020. 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 businesses and citizens must adjust to the changes that came into effect from 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 Protocol on Ireland/Northern Ireland, which forms part of the Withdrawal Agreement, means that no new procedures will apply to goods moving between Northern Ireland and Ireland (and the other Member States of the European Union).

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.

April 2021

EU Product Legislation

Question 1.
What EU product legislation applies to industrial products post-Brexit?

There has been no change to EU product legislation as a result of Brexit. Remember that it is the rules of the country that products are placed on the market that apply, not where they are manufactured. **This means that EU law still applies to all products placed on the EU market, including those from the UK.**

The following EU product legislation applies to products placed on the EU market:

	EU Legislation	Product Category
1	Directive 90/385/EEC	Active implantable medical devices (AIMDD)
2	Directive 92/42/EEC	Hot-water boilers
3	Directive 93/42/EEC	Medical devices (MDD)
4	Directive 98/79/EC	In vitro diagnostic medical devices (IVDD)
5	Directive 2000/14/EC	Noise emission in the environment by equipment for use outdoors
6	Regulation (EC) No 552/2004	Interoperability of the European Air Traffic Management network
7	Directive 2006/42/EC	Machinery (MD)
8	Directive 2009/48/EC	Safety of toys
9	Decision 2009/750/EC	Interoperability of Electronic Road Toll Systems
10	Directive 2010/35/EU	Transportable pressure equipment (TPED)
11	Regulation (EU) 305/2011	Construction products (CPR)
12	Directive 2013/29/EU	Pyrotechnic articles
13	Directive 2013/53/EU	Recreational craft and personal watercraft (RWC)
14	Directive 2014/28/EU	Explosives for civil uses
15	Directive 2014/29/EU	Simple pressure vessels (SPV)
16	Directive 2014/30/EU	Electromagnetic compatibility (EMC)
17	Directive 2014/31/EU	Non-automatic weighing instruments (NAWI)
18	Directive 2014/32/EU	Measuring Instruments Directive (MID)
19	Directive 2014/33/EU	Lifts and safety components for lifts
20	Directive 2014/34/EU	Equipment and protective systems intended for use in potentially explosive atmospheres (recast) (ATEX)
21	Directive 2014/35/EU	Low Voltage (LVD)
22	Directive 2014/53/EU	Radio equipment (RED)
23	Directive 2014/68/EU	Pressure equipment (PED)
24	Directive 2014/90/EU	Marine equipment (MED)
25	Directive 2016/797/EU	Interoperability of the rail system
26	Regulation (EU) 2016/424	Cableway installations
27	Regulation (EU) 2016/425	Personal protective equipment (PPE)
28	Regulation (EU) 2016/426	Appliances burning gaseous fuels (GAR)
29	Regulation (EU) 2017/746	In vitro diagnostic medical devices (IVDR)
30	Regulation (EU) 2017/745	Medical devices (MDR)
31	Regulation (EU) 2019/945	Unmanned aircraft systems and on third
32	Regulation (EU) 2019/1009	EU fertilising products

Question 2.
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 the CE mark. 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 comply 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 3.
What products should not display a CE mark?

Goods which are not covered by specific EU product regulations should not CE marked (e.g. sockets are not covered by EMC, Radio Equipment or Low Voltage Directives or harmonised standards). Compliance for these products is determined according to other reference documents such as national standards, Commission recommendations, codes of practice, etc.

All products placed on the EU market must comply with the General Product Safety Directive (GPSD) in so far as the product isn't subject to specific safety requirements imposed by other legislation. Products within scope of the General Product Safety Regulations should not be CE marked.

Products Imported from the UK

Question 4.
What rules apply to products which are not CE marked?

Ireland remains part of the EU single market and customs union and all products imported from the Great Britain (England, Scotland & Wales) must conform with EU rules.

Any industrial product imported from Great Britain that is covered by the product legislation listed in the answer to Question 1 must comply with the relevant directive or regulation and be CE marked if they are to be placed legally on the EU market.

This means that industrial products imported from Great Britain require:

- an EU declaration of conformity
- the correct CE marking
- certification by an EU notified body if required by the relevant legislation.

The importers name and contact must be included on the packaging and product information leaflet.

Question 5.
How will Brexit impact my supply chain?

If you source products or components from Great Britain based suppliers, then you will need to consider the impacts of customs processes and potential supply disruption.

Goods which origi¬nate from the Great Britain may not be counted toward “EU content” under rules of origin; this may impact your ability to access preferential tariff arrangements which the EU has in place with other jurisdictions.

If your suppliers rely on certification or conformity assessment from UK based certification bodies or UK accredited test laboratories, you will need to check that their certification is acceptable under EU law.

The Protocol on Ireland/Northern Ireland avoids a hard border on the island of Ireland and most of the changes applying to trade with GB will not apply to trade with NI. This means that Goods moving between NI & EU will largely continue to do so as before.

Exporting to the UK

Question 6.
What rules will apply to industrial products in the Great Britain post-Brexit?

The UK put in place a new legal framework for product certification whereby UK legislation replaced EU legislation. It applies to products placed on the Great Britain market (England, Scotland, and Wales). The Protocol on Ireland/Northern Ireland means that UK legislation does not generally apply to the Northern Ireland market.

UK product legislation effectively transposed EU product legislation into UK law, so many of the details are similar. In general:

- The UKCA mark replaces the CE mark
- UK approved bodies replace EU notified bodies
- UK designated standards replace EU harmonised standards
- UK Declaration of Performance replaces EU Declaration of Conformity
- UK customers of EU manufacturers will become importers under UK law.

Products intended for the UK market must comply with the requirements of all applicable UK product legislation.

Most new products come within the scope of one or more of the UK product regulations listed below. However, some work equipment that is not powered or used to lift - such as hand tools, racking and ladders - does not come within the scope of these regulations. Instead these products must meet section 6 of the Health and Safety at Work etc Act 1974.

- Section 6 of the Health and Safety at Work etc Act 1974 (HSW Act)
- Supply of Machinery (Safety) Regulations
- Electrical Equipment Safety Regulations
- Lifts Regulations
- Pressure Equipment Regulations and Simple Pressure Vessels (Safety) Regulations
- Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations
- Gas Appliances (Supply) and Enforcement Regulations
- Cableway Installations Supply and Enforcement Regulations
- The Explosives Regulations 2014 (Amendment) Regulations 2016
- Pyrotechnic Articles (Safety) Regulations
- Personal Protective Equipment (Supply) and Enforcement Regulations
- Electromagnetic Compatibility Regulations
- Construction Products Regulations
- Medical Devices Regulations
- Noise Emission in the Environment by Equipment for use Outdoors Regulations
- Non-Road Mobile Machinery (Emission of Gaseous and Particulate Pollutants) Regulations
- Radio Equipment Regulations
- General Product Safety Regulations
- Toys (Safety) Regulations
- Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations

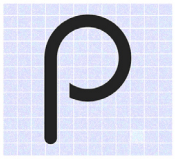
If you wish to continue exporting to Great Britain post-Brexit, you will need to familiarise yourself with the requirements of the amended regulations. You should also consult the UK Government website (*www.gov.uk/transition*) regularly for the latest information.

Question 7.
What product certification marks must be used for products exported to GB?

For most products placed on the UK market you will be required to use the UKCA mark, which replaces the CE mark used in the EU.

However, there are two exceptions:

- The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment (Amendment) (EU Exit) Regulations 2020 introduced 'rho mark' as the conformity mark for transportable pressure equipment in UK to replace EU pi mark.



- The Merchant Shipping (Marine Equipment) (Amendment etc.) (EU Exit) Regulations 2019 introduced 'red ensign mark' as the conformity mark for marine equipment in UK to replace EU wheel mark.

Question 8.
Can I use CE marking when exporting to Great Britain?

The UK Government has indicated that CE marked products can still be placed on the Great Britain market up to 31 December 2021. 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. From 1 January 2022 CE marked products or devices will no longer be accepted for the Great Britain market.

The UK Government has also indicated that certain CE marked product will continue to be accepted for limited periods after 1 January. These include:

- **Medical devices** (including devices requiring certification under the RED or EMCD) will be accepted in GB up to 30 June 2023. They must also have a valid EU Declaration of Conformity and be certified by an EU notified body to EU harmonised standards where required by EU law and be registered with the MHRA. From 1 July 2023 CE marked medical devices will no longer be accepted for the Great Britain market.

- **Marine Equipment** (certified under the MED) will be accepted in GB up to 31 December 2022. They must also have a valid EU Declaration of Conformity, be certified by an EU notified body to EU harmonised standards where required by EU law and marked with the EU 'Wheel mark'. From 1 January 2023 EU certified marine equipment will no longer be accepted for the Great Britain market.

- **Transportable Pressure Equipment** (certified under the TPED) will be accepted in GB up to 31 December 2022. They must also have a valid EU Declaration of Conformity, be certified by an EU notified body to EU harmonised standards where required by EU law and marked with the EU 'Pi mark'. From 1 January 2023 EU certified marine equipment will no longer be accepted for the Great Britain market.

Question 9.

Can my product have more than one marking on it?

You may use both EU and UK marking on your products once your products meet the essential requirements of the relevant EU and UK product legislation. To apply 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 equivalent UK product legislation. The product will need to be to have both a valid EU Declaration of Conformity and a valid UK Declaration of Conformity.

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.

The same applies for other conformity marks:

- The EU 'Pi mark' and UK 'rho mark' can be applied to transportable pressure equipment once it complies with the EU TPED and the equivalent UK regulation.
- The EU 'Wheel mark' and the UK 'red ensign mark' can be applied to marine equipment once it complies with the EU Marine Equipment Directive and the equivalent UK regulation.

Economic Operators

Question 10.
What has changed for businesses buying products from Great Britain based manufacturers?

The UK has left the EU and EU rules for third countries now apply to Great Britain. (The Protocol on Ireland/Northern Ireland means that EU product legislation continues to apply there, and it is treated as if it is part of the EU Single Market).

This means that you are now an **importer** and have additional responsibilities that you did not have before and you should become familiar with these as soon as possible.

You should also engage with your GB suppliers as you are required to hold additional information.

Question 11.
What additional responsibilities do I have if I buy products from a GB supplier?

The additional responsibilities of an importer include:

- You shall only place products that complies with EU rules on the market.
- Before placing products on the market, you shall ensure that:
  - the appropriate conformity assessment procedure has been carried out by the manufacturer
  - the manufacturer has drawn up the technical documentation
  - the product bears the correct CE marking and is accompanied by the required documents
  - that the manufacturer has complied with the requirements set out in the relevant product legislation.
- You will be required to indicate on the product:
  - your name
  - registered trade name or registered trademark
  - the postal address at which you can be contacted, which shall be in English or Irish.
- You will have to ensure that the products are accompanied by instructions and safety information in English or Irish.
- You will be required to keep a copy of the EU declaration of conformity and ensure that the technical documentation can be made available to market surveillance authorities for 10 years after the last of the product has been placed on the market.

General information on these obligations are given in Decision No 768/2008/EC of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC with more specific information given in the relevant EU product legislation.

You can also get more information in the EU Blue Guide (*https://ec.europa.eu/growth/content/%E2%80%98blue-guide%E2%80%99-implementation-eu-product-rules-0_en*).

Trading with Northern Ireland

Question 12.
How does Brexit impact trade with Northern Ireland?

The Protocol on Ireland/Northern Ireland ('the Protocol') ensures that there is no hard border on the island of Ireland, safeguarding the Good Friday Agreement, 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 and 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 13.
Do I need to use the new 'CE UK(NI)' mark when selling products to Northern Ireland?

EU product legislation continues to apply in NI as if it were still in the EU. This includes RAMS and the specific product legislation. Any product that meets the essential characteristics of the relevant EU legislation and has:

- been CE marked
- a valid EU Declaration of Conformity
- been certified by an EU notified body if require by RED or EMCD can be placed on the NI market.

Irish manufacturers who CE mark their products **do not** need to use the 'CE UK(NI)' mark when placing them on the NI market and there are **no changes** for Irish distributors selling CE marked products to NI customers.

Question 14.
Are there any changes if I buy products or devices from Northern Ireland?

EU product legislation continues to apply to products manufactured in Northern Ireland or placed on the Northern Ireland market. They still need to have to have an EU Declaration of Performance, be CE marked and certified by an EU notified body where required by the RED or EMCD.

This means that Irish business buying CE marked products in NI can continue to place these legally on the EU market. However, be aware that products marked with the 'CE UK(NI)' mark cannot be placed on the EU market, so cannot be sold in Ireland.

As EU product legislation continues to apply in Northern Ireland, any EU business buying from an NI manufacturer or distributor remain distributors under EU law and have no additional responsibilities.

Third Party Certification & Notified Bodies

Question 15.
I am a manufacturer of a product for which the certificate has been transferred from a UK notified body to an EU-27 notified body. Does the EU declaration of conformity and product labelling need to be updated?

Yes, both the EU declaration of conformity (drawn up by the manufacturer) and product labelling must be updated.

When a certificate has been transferred, both the EU Declaration of Conformity (drawn up by the manufacturer) and the Notified Body Certificate must be updated to mention 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 16.
Does the UK NB number on the device need to be changed for products manufactured before the transfer of the certification to an EU NB?

If the product documentation is in order, there is no need to change the notified body identification number for products already placed on the EU market.

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

Since the end of the transition period on 31 December 2020 any products certified by the UK notified body can no longer be placed on the EU market.

Question 17.
Do I have to use a notified body to certify my products?

It is the responsibility of the manufacturer to demonstrate that a product, before it is placed on the market, conforms to these legislative requirements.

Decision No 768/2008/EC of 9 July 2008 on a common framework for the marketing of products and repealing Council Decision 93/465/EEC gives legal effect to the framework for conformity assessment to be applied in Union law for specific products. It sets out a number of different modules which may be applied to demonstrate an industrial product meets the essential characteristics set out in the relevant product legislation.

Most of these modules require a manufacturer to have their product certified by an independent third party - a notified body or a notified test laboratory. In Module A the manufacturer fulfils these obligations and declares their sole responsibility that the products concerned satisfy the requirements of the EU legislation that applies to them. The manufacturer is not required to use an EU notified body for conformity assessment when using this module.

There are no EU notified bodies for the Low Voltage Directive as all products covered by it are assessed using Module A.

The CPR uses Assessment and Verification of Constancy of Performance (AVCP) to assess products and control the constancy of the assessment results. Any products assessed under AVCP System 4 do not require the use of a notified body or notified laboratory.

Certification by Manufacturers

Question 18.
When are manufacturers allowed to certify their own products?

Manufacturers are allowed to certify their own products where the legislation provides for equipment and devices to undergo conformity assessment in accordance with Module A (internal production control).

It also applies to construction products to which AVCP System 4 applies.

Question 19.
What are the requirements for manufacturers to certify their own products?

- Identify which directives may be applicable.
- If more than one directive or regulation applies to a product it has to conform with requirements of all applicable regulations or directives.
- When all requirements have been established, the conformity of the product to the essential requirements of the Directive(s) need(s) to be assessed. This usually involves assessment and/or testing and may include an evaluation of the conformity of the product to the harmonised standard(s). Where the legislation requires these to be carried out under Module A, there is no requirement for the manufacturer to use an EU notified body for this.
- Technical documentation relating to the product or range of products, must be compiled. This information should cover every aspect relating to conformity and include details of the design, development, and manufacture of the product.
- Check that no other national requirements exist in the countries the products are to be sold (e.g. national standards, packaging/labelling requirements, etc.) and ensure that any national requirements are met.
- The EU declaration of conformity must be completed. It should include:
  - the name and address of the manufacturer
  - details of the product (model, description, and the serial number where applicable)
  - a list of applicable Directives and standards that have been applied
  - a statement declaring that the product complies with all of the relevant requirements
  - the signature, name, and position of the responsible person
  - the date that the declaration was signed.
- Finally, affix the CE marking to the product and supply user operating instructions. When this has been done, the product can be placed legally on the EU market.

Question 20.
How does the UK's withdrawal from the EU affect UK manufacturers certifying their own products?

EU legislation applies to products placed on the EU market irrespective of where they are manufactured. Manufacturers from a non-EU country (including those in the UK) must affix the CE mark when exporting to the EU, where this is required by the relevant EU directives or regulations.

UK manufactured products that have undergone a conformity assessment procedure (including the product and quality assessment procedure) by the manufacturer in accordance with Module A (or AVCP System 4 for the CPR) can be certified by the manufacturer and the CE mark applied once they have met the requirements of the relevant EU product legislation.

Question 21.

I use a UKAS accredited test laboratory when certifying my products. Are their test certificates valid for placing goods on the EU market?

Many Irish manufacturers use UK laboratories to use demonstrate product performance as meeting regulatory requirements. This applies both to manufacturers self-certifying their products and to manufacturers using a UK test result as part of a broader EU regulatory submission.

The UK Accreditation Service ceased to be a national accreditation body within the meaning and for the purposes of Regulation No 765/2008 on Accreditation and Market Surveillance (RAMS) from the end of the transition period on 31 December 2020. As a consequence, its accreditation certificates will be no longer be considered as 'accreditation' within the meaning of Regulation No 765/2008 and will be no longer valid or recognised in the EU pursuant where Regulation No 765/2008 applies. This means that UKAS accredited test laboratories cannot be used where RAMS applies.

UKAS is still a member of European Accreditation (EA) and the mutual recognition arising from EA membership still applies to UKAS. This means that UKAS accredited test laboratories can still be used for conformity assessment where RAMS does not apply. UKAS accredited laboratories can continued to be used to demonstrate conformity to national regulations.

You can get further information on accreditation from the Irish National Accreditation Board web-site (*www.inab.ie*).

Standards

Question 22.
Are British Standards still recognised in Ireland?

The NSAI is the National Standards Body in Ireland and BSI is the National Standards Body in the UK. Both the BSI and NSAI are members of the European Standards Organisation CEN and CENELEC who develop and publish European Standards (EN). Each European country is obliged to adapt the EN and withdraw any conflicting National Standard within 6 months of the EN being published. In the UK the BS adopt the standard and it is then published as a BS EN. In Ireland NSAI adapt the standard and it is published as I.S. EN.

The use of British Standards in Ireland has a number of different legal bases, only some of which are directly affected by Brexit. There are areas where it is no longer permitted to use a British Standard to demonstrate conformity or performance and there are other areas where the use of British Standards remains unaffected.

As a general guideline, in areas where Member States have competency (i.e. where there is no EU legislation and national law applies) there is no restriction on the use of British Standards once they are permitted under national legislation. A range of standards are referenced in Irish legislation. These include:

- International standards (ISO, etc.),
- European Standards (EN).
- Harmonised European Standards (hEN),
- Irish national standards (I.S.),i.e. a standard specification declared or deemed to have been declared under section 16 of the National Standards Authority Act, 1996,
- National standards from other countries (including British Standards, BS), and
- Standards developed by trade bodies and other entities.

They are also referenced in other documents, including guidelines, by-laws, regulations, standards (i.e. guidance documents published by State bodies).

This means that where Irish legislation permits or mandates the use of a BS for areas not covered by EU law there should be no change to their recognition or use in Ireland.

Question 23.
Where are British Standards no longer recognised?

The EU Commission has indicated that the use of a British Standard on an EU Declaration of Conformity where a harmonised European Standard (commonly referred to as a 'harmonised standard') must be used for product certification would be a non-compliance under EU product legislation.

This means that any products where a 'harmonised standard' must be used to demonstrate conformity under the Low Voltage Directive, Radio Equipment Directive, or EMC Directive, a national standard from an EU or EEA country must be used (e.g. Irish Standard I.S. EN or German Standard DIN EN could be used but a BS EN could not).

Further Information

For general information on Brexit readiness in the area of standards and certification:
www.nsai.ie/brexit/brexit-readiness

For NSAI targeted information, see our Brexit resources section:
www.nsai.ie/brexit/brexit-resources

Any queries or questions related to standards and certification post-Brexit can be directed to:
BrexitUnit@nsai.ie

The Irish Government website acts as a portal for information from Government Departments and State Agencies:
www.gov.ie/en/campaigns/b2c18-getting-ireland-brexit-ready

The Department of Enterprise, Trade and Employment has information on Brexit supports for Irish businesses:
www.enterprise.gov.ie/en/What-We-Do/Supports-for-SMEs/Brexit-Supports

The EU Commission has information on the future relationship with the UK:
ec.europa.eu/info/relations-united-kingdom_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:
eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016XC0726(02)&from=BG

UK Government has information concerning Brexit changes for the UK market:
www.gov.uk/transition

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