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New UKCA and UKNI product markings

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Contents:

Contents

Summary

The CE mark is placed on a wide range of products to show they are compliant with EU regulatory requirements, including toys, electrical equipment, and machinery. In most cases, the CE mark can be applied to products tested by the manufacturer. However, for some products, there is a legal requirement for the product to be assessed by a third-party assessment body (a "notified body") to confirm they meet relevant regulatory requirements. A separate Library briefing paper, "Brexit: product standards and safety markings" (CBP583) provides background information on the EU product safety regime.

Having left the EU, and with the transition period about to end, the UK Government has continued to push forward with plans to revise the product marking regime and implement a new, post-Brexit mark for products sold in Great Britain (England, Wales and Scotland). This new UKCA (UK Conformity Assessed) mark can be used from **1 January 2021**. To allow businesses time to adjust to the new requirements there are transitional measures, but from **1 January 2022** only products with UKCA marking will be accepted in Great Britain. The UKCA mark will cover most goods which currently require CE marking, but to be eligible to use the new mark the business must use a UK-based notified body. Importantly, businesses only using the UKCA mark will not be able to sell in Northern Ireland or the EU.

From **1 January 2021**, when the Northern Ireland Protocol comes into force, Northern Ireland businesses will have "unfettered access" to the whole of the UK market as well as the guaranteed ability to trade freely within the EU Single Market. This arrangement reflects the unique circumstances of Northern Ireland and the Belfast (Good Friday) Agreement. Consequently, a separate marking regime will exist for Northern Ireland, with products requiring CE marking or a new UKNI mark. Three important points should be noted. First, the UKNI mark cannot be placed on products unless there is a specific legislative requirement to do so. Second, the UKNI marking must accompany another conformity marking; it never appears on a product alone. Finally, a business can only use a UKNI mark if their product has undergone mandatory third-party conformity assessment by a body based in the UK.

Therefore, a UK manufacturer may need to use different markings when selling to different markets. A summary of the position from 1 January 2021 is outlined below.

UKCA mark (only):

- The business can sell in the UK.
- However, the business cannot sell in Northern Ireland and cannot sell in the EU.
- To use a UKCA mark, the business must use a UK-based notified body.

UKNI mark

- The business can sell in Great Britain.
- The business can sell in Northern Ireland but only if coupled with the CE mark.
- However, the business cannot sell in the EU.
- To use a UKNI mark, the business must use a UK-based notified body.

CE mark (only):

- A business can still sell in Great Britain until 31 December 2021, provided it meets the criteria (see below) and EU and UK requirements for the product remain the same.
- The business can sell in Northern Ireland.
- The business can also sell in the EU.
- To use a CE Mark, the business must use an EU-based notified body.

Amidst calls for greater clarity, on 1 September 2020 the Department for Business, Energy & Industrial Strategy (BEIS) issued guidance on Using the UKCA mark from 1 January 2021. This guidance covers the use of conformity assessment markings, notified bodies, the appointment of authorised representatives and the responsibility of distributors. It explains what businesses will need to do in order to get ready for the change of regime. On 30 October 2020, BEIS published separate guidance on "Using the UKNI Marking from 1 January 2021".

Agreement may be reached on an UK-EU trade agreement in the few remaining weeks of the transition period and, if so, the terms of that agreement may impact on product conformity assessments on imports and exports. For example, a trade agreement might include a comprehensive system of mutual recognition of product standards and conformity marks. However, the Government has indicated that it would be sensible for UK manufacturers to work on the assumption that there will be no change to the new regulatory regime outlined in the most recent guidance and that this will apply from 1 January 2021.

This House of Commons briefing paper provides information on the use of the new UKCA and UKNI marks, the role of notified bodies, and the responsibilities of economic operators (i.e. manufacturer, importer and distributor).

1. EU product marking regime

This section provides a summary of the EU product safety regulatory scheme. UK businesses wishing to place their goods on the EU market after 1 January 2021 must continue to use EU conformity markings, for many goods this will be the CE mark. For as long as the Northern Ireland Protocol is in force, the CE mark will also continue to be used in Northern Ireland.

CE marking symbol shows that the manufacturer has taken all necessary measures to ensure that the product complies with the applicable safety legislation. It plays a crucial part is the New Legislative Framework for the EU internal market for goods, which came into force at the beginning of 2010.

1.1 EU "New Approach" regulatory scheme

EU product safety legislation is based on the "New Approach" for the marketing of products. Directives adopted under the "New Approach to technical harmonisation and standards" specify in general terms "essential" safety requirements, and European standardisation bodies produce standards which define these technical requirements.

The "New Legislative Framework"(NLF), adopted in July 2008, built on the New Approach. It completed the overall legislative framework with all the necessary elements for effective conformity assessment, accreditation and market surveillance including the control of products from outside the EU. In a nutshell, the NLF establishes a common set of principles to make legislation on the Single Market for goods clearer, more consistent and more understandable. It aims to:

- improve market surveillance rules to better protect both consumers and professionals from unsafe products, including those imported from outside the EU;
- boost the quality of and confidence in the conformity assessment of products by setting clear, transparent rules for the accreditation of conformity assessment bodies;
- clarify the meaning and use of CE marking and enhance its credibility; and
- establish a common legal framework for industrial products in the form of a 'toolbox' of measures for use in future legislation. (This includes definitions of terms commonly used in product legislation, and procedures to allow future sectorial legislation to become more consistent and easier to implement).

Certain goods (including toys, machinery, medical devices, electrical and electronic equipment) are subject to EU-wide product-specific rules contained in the various "**New Approach Directives**". The directives define essential requirements related to health, safety and environmental issues. Products must meet these "essential requirements" in order to be placed on the EU market.

Three European Standards Organisations, CEN (European Committee for Standardisation), CENELEC (European Committee for Electrotechnical standardisation), and ETSI (European Telecommunication Standards Institute) enable these requirements to be fulfilled using **harmonised European standards**. If industries follow harmonised standards, they benefit from a presumption of conformity to the essential requirements set in the directives.

Whilst a great many of the safety-orientated harmonised measures for manufactured products fall under the NLF, some do not (notably motor vehicles and medicines). Food and agricultural products have quite separate legal regimes.

The EU's Blue Guide on EU product rules (last updated in 2016) explains how to implement EU product legislation and is intended for EU and EEA member states. Interested parties might include manufacturers, importers, distributors, conformity assessment bodies, trade and consumer associations.

A separate Library briefing paper, "Brexit: product standards and safety markings" (CBP583) (in particular section 2) provides detailed information on the current regime and the UK's conformity with product standards and safety markings.

1.2 Conformity assessment

Box 1: What is conformity assessment?

This is the process by which persons can legally place safe and compliant products onto the European market (or bring them into use) for the first time.

Conformity assessment is a common feature of the **New Approach Directives** concerned with product safety, and includes various checks on the:

- design and construction of products to meet essential requirements which normally are for health and safety;
- and being able to demonstrate this through a technical file;
- before declaring and certifying a products' conformity with all relevant Directives, and affixing **CE marking** to the product.

Some products can be **self-certified** through this process, but others must undergo specific conformity assessment procedures involving third parties known as **Notified or Conformity Assessment Bodies**, before the manufacture can declare conformity.

The aim of conformity assessment is to create consumer confidence in goods, services, processes and management systems. To assure consumers that what is being supplied meets the expectations specified or claimed.

As outlined in **Box 1**, EU-wide product-specific rules include arrangement for conformity assessment; the testing and inspection of goods to ensure they meet relevant requirements. These products,

which must be certified by a notified or conformity assessment body,[1] must bear a CE mark before they are placed on the EU market. A CE mark is a manufacturer's declaration that a product meets the essential safety requirements set out in the relevant New Approach Directive. Specifically, the CE mark:

- shows that the manufacturer has checked that these products meet EU safety, health or environmental requirements;
- is an indicator of a product's compliance with EU legislation;
- allows the free movement of products within the European market.

Importantly, the CE mark is accompanied by a Declaration of Conformity signed by the manufacturer (or its representative).

1.3 Role of notified bodies

In most cases, the CE mark can be applied to products tested by the manufacturer. However, for some products there is a legal requirement for the product to be assessed by a "notified body" (a third-party assessment body) to confirm they meet relevant regulatory requirements.[2]

Each EU Member State is required to appoint a single national accreditation body to carry out the accreditation of notified bodies. The UK Accreditation Service (UKAS) is appointed by BEIS to be the national accreditation body.[3]

In the event of a no trade agreement scenario, the EU has said it will stop recognising the competency of UK-based notified bodies to assess products for the EU market. In effect, manufacturers who continue to use UK-based notified bodies will no longer be able to apply the CE mark.

In a similar vein, the Government intends to reclassify UK notified bodies as **UK Approved bodies**. These bodies will be able to assess products against relevant UK requirements and issue the new UKCA mark to compliant products. Further information is provided at **Section 2.1** of this paper.

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1 A notified body is an organisation that has been designated by an EU Member State (the designating authority) to assess whether manufacturers and their products meet the requirements set out in legislation. For example, in respect of medical devices, the Medicines and Healthcare Products Regulatory Agency (MHRA) is the designating and competent authority in the UK.

2 A **notified body** is an organisation designated by an EU member state to assess the conformity of relevant products before being placed on the market. Notified bodies are usually given the right to carry out a conformity assessment following its own assessment by a national accreditation body.

3 UKAS is appointed as the national accreditation body by Accreditation Regulations 2009 (SI No 3155/2009) and EU Regulation (EC) 765/2008 and operates under a Memorandum of Understanding with the Government through the Secretary of State for BEIS

1.4 CE marking scheme

Box 2: CE marking

CE marking is the manufacturer's declaration that the product meets EU standards for health, safety, and environmental protection.

CE marking is mandatory for those products covered by the scope of one or more of the New Approach Directives.[4] Even if a product is manufactured outside the EEA, it must still bear the CE mark if it comes under the scope of a directive requiring CE marking.[5]

CE marking applies to 24 different product categories, ranging from electrical equipment to toys and from explosives to medical devices. Each product falls under one or more Directives, which determine the specific requirements that the product must meet in order to be CE-marked. It is the responsibility of the manufacturer to ensure that the product is appropriately marked. By placing CE marking on a product, the manufacturer declares the product's conformity with the applicable EU legal requirements. Some products can be self-certified, others must be examined by a notified conformity assessment body before the manufacturer can declare conformity.

The CE mark indicates that the product meets EU safety, health or environmental requirements. Importantly, it guarantees the free movement of safe products within the European market. The marketing and sale of **products which carry a CE mark cannot be restricted within the EU and the broader EEA** unless there is evidence of non-compliance with the underlying EU legislation justifying such restriction.

Importantly, a CE mark does not mean that a product complies with all other EU legislation that applies to that product. CE marking is in addition to other legal requirements in respect of consumer protection, product safety, environmental protection etc.

4 A full list of directives can be found on the Europa website
5 EU New Approach Directives guidance can be viewed on the Europa website

1.5 Authorised representatives

Businesses may (where permitted in the relevant legislation) appoint "authorised representatives" (or "responsible persons") to carry out certain tasks related to product safety (e.g. to maintain a product's technical documentation). The authorised representative might also affix a marking (such as a CE mark) to a product to indicate its conformity with the applicable legislative requirements.

1.6 Not all products sold in the EU need to bear CE marking

The CE marking applies to a wide range of products, but not all products sold in the EU are required to bear a CE mark. Only the product categories subject to specific New Approach Directives are required to be CE marked (in total there are 24 different product categories).

Other product categories may be subject to special rules, for example:

- Pharmaceutical products
- Chemicals
- Automotive goods
- Aerospace

2. Background: changes to UK product marking regime

2.1 Introduction

Preparations are taking place across government to ensure regulatory continuity in the event of the UK leaving the EU without a trade agreement. This includes both the designation of standards to support regulations under the NLF and the introduction of a new UK regulatory mark, the UKCA mark, that will be affixed to products or their packaging.

According to the BSI (British Standards Institution), the role of the new UKCA mark will be to "support the authorities and provide clarity to manufacturers placing products on the market in the UK post-Brexit – but only in the case that the UK leaves the EU without a deal."[6]

On 10 July 2020, the Government published guidance on "Marking, labelling and marketing standards from 1 January 2021", this guidance sets out the general requirements across the UK. Further information is set out below.

2.2 UK-based notified bodies

EU will stop recognising competency of UK-based notified bodies

From 1 January 2021, the EU has said it will stop recognising the competency of UK-based notified bodies to assess products for the EU market.

Specifically, on 22 January 2018, the European Commission (EC) issued a Notice setting out the effect Britain's withdrawal from the EU may have on product safety standards in the event of a no deal, Notice to stakeholders – Withdrawal of the UK and EU rules in the field of industrial products. In this Notice, the EC states:

> "[…] economic operators are advised to take the necessary steps to ensure that, where the applicable conformity assessment procedures require the intervention of a Notified Body, they will hold certificates issued by an EU-27 Notified Body".

In the absence of any other arrangement, the EC outlined its position as follows:

> "[…] where economic operators hold certificates issued by a UK Notified Body prior to the withdrawal date and plan to continue placing the product concerned on the EU-27 market as from the withdrawal date, they are advised to consider either to apply for a new certificate issued by an EU-27 Notified Body or organising a transfer […] of the file from the UK Notified Body to an EU Notified Body".

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6 BSI, "Preparation for a possible "No Deal" Brexit – business as usual for standards", 5 February 2019, [online] (accessed 1 December 2020)

Simply put, since EU legislation requires a notified body to be based in the EU, **UK-based notified bodies will no longer be able to apply the CE mark after 31 December 2020.** Consequently, UK manufacturers of industrial products wishing to sell to the EU must instruct EU based notified bodies. To demonstrate the potential impact of this Notice, almost half of all medical device products certified in the EU currently use UK notified bodies.

UK exporters to the EU are advised by the Government to check what steps (if any) their UK notified body is taking so that they can continue exporting to the EU without having to change to a new EU notified body. For example:

- Some UK notified bodies already have contingency plans in place to ensure that from the end of the transition period, global clients can continue to use them as their European notified body.
- EU notified bodies, although they must be established in an EU country, can operate in third countries. It may be possible, therefore, for a UK-based body to establish a relationship with one based in the EU 27 and thus carry out its assessments in respect of both the EU and UK systems, given that the standards will be identical.
- Finally, the EU has bilateral arrangements whereby it recognises that conformity assessment bodies established in partner countries can give authoritative assessments on products vis-à-vis EU regulations. However, even where such arrangements exist they are often not comprehensive.

If a UK notified body is not doing anything, then Government guidance suggests that the UK exporter either:

- has the product reassessed by an EU notified body; or
- arranges for information held by the existing UK notified body to be transferred to an EU notified body so it can issue a fresh certificate.[7]

Introduction of new "UK Approved Bodies"

The UK Government intends to reclassify UK notified bodies as UK Approved Bodies. These bodies will be eligible to assess products against relevant UK requirements and issue the new UKCA mark to compliant products. Businesses will be able to continue to work with a UK-based notified body and apply the UKCA mark on its product from 1 January 2021. However, this is only an option if the business is only selling its product in Great Britain (England, Wales and Scotland).

UK products being exported to the EU which currently require CE marking, will continue to require CE marking to demonstrate compliance with the relevant EU regulatory requirements.

[7] The transfer of an existing certificate to an EU notified body will require the four-digit notified body number on the product to be updated. This will not be necessary, however, for products manufacturers or on the market before the transfer took place.

2.3 Separate certificates of conformity for EU and UK markets

Products to be sold on both the UK and EU markets will eventually require separate **certificates of conformity** for the two markets. UK Government guidance states that:

> "[…] if a manufacturer transfers its certificate to the EU it may be unable to sell in the UK from 1 January 2022. UK and EU notified bodies are required to share information when requested by a certificate holder which should facilitate the issuing of new certificates of conformity."

However, the guidance acknowledges that the process may take a long time. For this reason, the Government advises UK manufacturers to start preparing now.

In addition, some economic operators (i.e. manufacturers, importers and authorised representatives) currently operating from the UK might see their designation change under CE marking legislation as well as their relevant obligations. For example, after the transition period, EU distributors established in the UK may become importers under CE marking legislation in relation to the products that they place on the EU market. See **section 3** of this paper for further detailed information.

2.4 Introduction of new UKCA mark

Box 3: New UKCA mark: The UK Conformity Assesses (UKCA) marking

This is the design for the UK marking for certain products to be sold in the UK, which would replace the CE marking in the event the UK leaves the EU without a deal.

The UKCA (UK Conformity Assessment) mark is the new UK product marking that will be required for certain products being placed on the market in Great Britain (England, Wales and Scotland). It covers most products that previously required the CE mark. However, it will not be recognised in the EU market; products that require CE marking will still need a CE marking to be sold in the EU.

The UKCA mark will come into force on 1 January 2021, although CE marking will continue to be recognised in the UK until the end of 2021 provided UK and EU regulations remain aligned. This would include

products assessed by an EU-recognised body. However, from the beginning of 2022 only products with UKCA marking will be accepted in Great Britain. The following points should be noted about the new UKCA mark:

- First, where a UKCA mark is required, it will be underpinned by the same British standards as current legislation.
- Second, the concept of "harmonised standards" will be transferred into the UK legal order to become identical "**designated standards**". In effect, from 31 December 2020 the Secretary of State will cite designated standards for the purposes of providing a presumption of conformity with the applicable regulation, in the same way as the European Commission cites European standards.

Further information is provided in **section 4** of this paper.

Government guidance on "Using the UKCA mark from 1 January 2021" was published on 1 September 2020.[8]

2.5 Introduction of a new UKNI mark

Box 4: New UKNI mark

This is the design for the UKNI marking for certain products to be sold in Northern Ireland.

The Northern Ireland Protocol ("the Protocol") is expected to come into force on 1 January 2021. A Command Paper was published on 20 May 2020, "The UK's approach to the Northern Ireland Protocol". As stated by the UK Government, the Protocol is designed to be:

> "[…] a practical solution to avoid a hard border with Ireland whilst ensuring the UK, including Northern Ireland, leaves the EU as a whole, enabling the entire UK to benefit from future Free Trade Agreements (FTAs). There will be special provisions which apply only in Northern Ireland while the Protocol is in force."[9]

The UK Government will guarantee in legislation "unfettered access for Northern Ireland's businesses to the rest of the UK internal market from

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8 Department for Business, Energy and Industrial Strategy, "Guidance: Using the UKCA mark from 1 January 2021: Find out if you will need to use the new UKCA marking and how to use it", 1 September 2021, [online] (accessed 1 December 2020)

9 Cabinet Office, "Moving goods under the Northern Ireland Protocol: Introduction", 7 August 2020, [online] (accessed 1 December 2020)

1 January 2020, ensuring that trade from Northern Ireland continues as it does now.[10] Those goods will be able to be placed on the market in England, Wales and Scotland, whether certified against EU or UK rules.[11] This special treatment will be available only to Northern Ireland businesses.[12]

Consequently, a separate product marking regime will exist for Northern Ireland. For as long as the Protocol is in force, Northern Ireland will align with all relevant EU rules relating to the placing on the market of manufactured goods. Businesses must show that their products meet those rules by using "conformity markings", for many goods this will be the CE mark.

However, a new UKNI conformity marking scheme will also come into force on 1 January 2020. The new UKNI mark (see **Box 4**) will apply to products placed on the market in Northern Ireland which have undergone mandatory third-party conformity assessment by a body based in the UK. Two important points should be noted:

- First, the UKNI mark cannot be placed on products unless there is a specific legislative requirement to do so.
- Second, the UKNI mark must accompany another conformity marking; it can never appear on a product alone.

On 30 October 2020, BEIS published separate guidance on "Using the UKNI Marking from 1 January 2021". This guidance does not address the policy position, which was examined in two previous BEIS papers, namely:

- Policy paper dealing with the position where goods are placed on the Northern Ireland market from Great Britain. (See Cabinet Office, "Moving goods under the Northern Ireland Protocol: moving goods from Great Britain to Northern Ireland", 7 August 2020.)
- Policy paper dealing with the position where goods are placed on the Northern Ireland market from the EU. (See Cabinet Office, "Moving goods under the Northern Ireland Protocol: Introduction", 7 August 2020).

Further detailed information about the new UKNI marking is provided in **section 5** of this paper.

10 Cabinet Office, "Policy paper: Moving goods under the Northern Ireland Protocol: Introduction", 17 November 2020, [online] (accessed 2 December 2020)
11 Ibid
12 This will include businesses headquartered in Great Britain with operations in Northern Ireland

3. From 2021: different product conformity markings for different markets

From 1 January 2021, UK businesses will have to use different conformity markings when selling their manufactured goods in different markets. **Box 5** provides a summary of the position.

Box 5: Separate product conformity markings (from 1 January 2021)

Subject to further guidance published by the UK Government, this is a summary of what mark a business will need for which market, and which notified body to approach to get it.

UKCA mark (only):

- The business can sell in the UK.
- However, the business cannot sell in Northern Ireland and cannot sell in the EU.
- To use a UKCA mark, the business must use a UK-based notified body.

UKNI mark:

- The business can sell in Great Britain.
- The business can sell in Northern Ireland but only if coupled with the CE mark.
- However, the business cannot sell in the EU.
- To use a UKNI mark, the business must use a UK-based notified body.

CE mark:

- A business can still sell in Great Britain until 31 December 2021, provided it meets the criteria (see below) and EU and UK requirements for the product remain the same.
- The business can sell in Northern Ireland.
- The business can also sell in the EU.
- To use a CE Mark, the business must use an EU-based notified body.

3.1 Placing goods on the GB market

In placing goods on the market in Great Britain (England, Wales and Scotland) the following points should be noted:

- The new UKCA mark can be used from **1 January 2021**. Broadly, UKCA marking copies CE marking so that most products to be placed on the Great Britain market that currently require a CE mark will require a UKCA marking.
- To use a UKCA mark, the business must use a UK-based notified body.
- To allow businesses time to adjust to the new requirements there are transitional measures, but from **1 January 2022** only products with UKCA marking will be accepted in Great Britain.

In terms of transitional measures, in most cases[13] businesses will still be able to use CE marking until **1 January 2022** if any of the following apply:

- they currently apply the CE marking to their goods on the basis of self-declaration;
- any mandatory third-party conformity assessment has been 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.

That said the Government is encouraging businesses to be ready to use the UKCA marking as soon as possible before this date.

For many products theses transitional measures offer a breathing space before businesses need to adjust to the new UKCA regime. However, the **transitional measures are subject to the proviso that UK and EU rules remain aligned.** This means that if the EU changes its rules and a business affixes a CE mark to its product on the basis of those new rules (and this is the only mark), the business will not be able to sell in Great Britain even before 31 December 2021. According to published guidance, the Government has no plans to diverge from EU requirements. Of course, this does not preclude the possibility that UK and EU requirements could diverge before 1 January 2022.

In some cases, the product must be UKCA marked **immediately from 1 January 2021**, if all the following criteria apply:

- It is for the market in Great Britain;
- it is covered by legislation which requires the UKCA marking;
- it requires mandatory third-party conformity assessment (as opposed to self-declaration); and
- a conformity assessment of the product has been carried out by a UK-based conformity assessment body and the business hasn't transferred its conformity assessment files from the UK body to an EU-based body before 1 January 2021.[14]

The obligation to use the UKCA mark will not apply to **existing stock**. Existing stock that has been fully manufactured and conformity marked can still be placed on the Great Britain market after 1 January 2021 with its existing markings and notified body numbers. For example, a product covered by a UK certificate of conformity, and which would ordinarily require a UKCA marking after 1 January 2021, can still be sold in the UK with a CE marking so long as it is from pre-existing stock fully manufactured before 31 December 2020 (i.e. the end of the transition period).

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13 Although construction products, medical devices, interoperability of the rail system and transportable pressure equipment are covered by the UKCA marking requirements, the transitional measures outlined above are not applicable

14 As outlined in section 2.3 of this paper, this will be the case if the product has been CE marked and certified by a UK-based notified body. The reason being that after 1 January 2021, the certificate obtained from that UK body will no longer be valid, as UK notified bodies will no longer be recognised by the EU.

On 1 September 2020, the Government issued guidance on "Placing manufactured goods on the market in Great Britain from 1 January 2021" (the guidance covers England, Wales and Scotland). It focuses on when manufacturers should include the new UKCA mark and how the mark should be used. There is separate guidance for medical devices, rail interoperability, construction products and civil explosives.

3.2 Placing goods on the Northern Ireland market

In Northern Ireland, EU conformity markings will continue to be used to show goods meet EU rules after **1 January 2021**. For most manufactured goods, this is the CE marking, but there are some other markings for specific products. UK manufacturers wishing to sell their goods in Northern Ireland should note the following:

- Manufactured goods being placed on the market in Northern Ireland using an EU conformity assessment body, must be **CE marked**.
- Manufacturers goods being placed on the market in Northern Ireland using a UK-based body to carry out mandatory third-party conformity assessment must also apply a UKNI marking. In other words, the product must be both **CE** and **UKNI marked**.
- The UKNI mark can never be applied on its own – it must always accompany an EU conformity marking.

Moving goods from Northern Ireland to Great Britain

As outlined in the published guidance, the UK Government will guarantee "unfettered access" for Northern Ireland's businesses to the whole of the UK market, without the need for additional approvals before placing goods on the market in the rest of the UK. They will be able to place "**qualifying goods**" on the market in Great Britain based on the conformity markings they use in Northern Ireland (i.e. they must be **CE** or '**CE and UKNI**' marked).

The UK Government has published details of its approach to unfettered access in guidance published on 7 August 2020, "Moving goods under the Northern Ireland Protocol: moving goods from Northern Ireland to Great Britain". The following points should be noted:

On 30 October 2020, the Government issued separate guidance for Northern Ireland, "Using the UKNI marking from 1 January 2021".[15] Further detailed information about the position in Northern Ireland is set out in **section 5** of this paper.

[15] Department for Business, Energy & Industrial Strategy, Using the UKNI marking from 1 January 2021, 30 October 2020, [online] (accessed 1 December 2020)

3.3 Placing goods on the EU market

Goods from England, Wales & Scotland

With regard to placing British goods on the EU market (i.e. goods from England, Wales and Scotland) from **1 January 2021**, the following points should be noted:

- Manufactured products that currently require a CE mark will continue to require a CE mark from 1 January 2021.
- Products only marked with the new UKCA mark will not be recognised on the EU market.
- A product with both the CE and UKCA markings can be placed on the EU market, provided they are fully compliant with both EU and UK regulations.[16] In other words, affected businesses could apply both marks in order to sell the same product/model in both the EU and GB markets (although this may involve changes to product design, packaging and labelling).

In addition, any mandatory conformity assessment must be carried out by an EU-recognised conformity assessment body. However, UK manufacturers wishing to sell to the EU after 1 January 2021 will not need to change their conformity assessment if **any** of the following apply:

- They self-declare the conformity of the product against applicable regulations.
- Any mandatory third-party conformity assessment was carried out by an EU-recognised notified body. (This includes both EU-based bodies and bodies in countries with which the EU has concluded a mutual recognition agreement).
- The certificate of conformity previously held by a UK body has been transferred to an EU-recognised notified body.
- They voluntarily use a testing body (including UK bodies) to test against European or international standards.

On 1 September 2020, the Government issued guidance on Placing manufactured goods on the EU internal market if there's no deal.

Goods from Northern Ireland

The UKNI marking will not be recognised on the EU market. A manufacturer placing goods on the EU market, must use the CE marking on its own, without the UKNI marking. In effect, a business will **not** be able to use the new UKNI marking scheme if they are placing goods on the EU market or the business is planning to use an EU body to carry out conformity assessments.

However, if manufacturers based in Northern Ireland (or their authorised representative) currently mark their goods on the basis of a supplier's "Declaration of Conformity", they will not need to make any changes.

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[16] However, for the EU market the CE mark must appear without the UKNI mark as goods bearing both the 'CE and UKNI' marks are not acceptable in the EU market. This means these goods must be manufactured to EU rules and cannot be assessed by a body based in the UK.

Their goods will continue to be valid on the UK and EU markets using the relevant conformity markings.

4. Detail of the new UKCA marking scheme

4.1 When to use the new UKCA mark?

- From **1 January 2021**, the UKCA mark will be the conformity assessment marking for goods placed on the market in Great Britain (England, Wales and Scotland – but not Northern Ireland).
- However, for most products, the CE marking will be accepted in the UK until **1 January 2022**. This means that manufactured goods being placed on the Great Britain market until the end of 2021 can be UKCA or CE marked.
- Manufactured goods placed on the GB market from 1 January 2022 must be UKCA marked.

4.2 Technical requirements

From 1 January 2021 the **technical requirements** (or "essential requirements") businesses 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 guidance acknowledges that these standards could change if/when the UK Government chooses to deviate from the existing EU rules, but for now, the requirements will continue as before.

The rules relating to the sizing and affixing of the UKCA mark remain largely the same as the CE mark. However, an important change is that from **1 January 2023**, the UKCA mark must be, in most cases, affixed directly to the product (as opposed to supporting packaging or documentation). A notable exception being medical devices. This transitional period is intended to give businesses enough time to build this requirement into their design process.

4.3 What products will the new UKCA mark apply to?

Broadly, the new UKCA mark mirrors the CE mark regime. Most manufactured products placed on the Great Britain market after the 1 January 2021 that would currently require a CE marking will require a UKCA marking (see **Box 6** below).

Box 6: What products will the new UKCA mark apply to?

As of **1 January 2021**, the UKCA marking regime will apply to all products that currently require a CE mark, with the addition of aerosol products. Specifically, the list includes the following product areas:

- Toy safety
- Recreational craft and personal watercraft
- Simple pressure vessels
- Electromagnetic compatibility

- Non-automatic weighing instruments
- Measuring instruments
- Lifts
- ATEX
- Radio equipment
- Pressure equipment
- Personal protective equipment (PPE)
- Gas appliances
- Machinery
- Outdoor noise
- Ecodesign
- Aerosols
- Low voltage electrical equipment
- Restriction of hazardous substances

Different rules relating to "specific" products

The following product areas are covered by the UKCA marking but some special rules also apply:

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

Different rules will apply to certain product categories listed in the UKCA guidance. In some cases, manufacturers may enjoy **extended deadlines for compliance** (e.g. manufacturers of medical devices do not need to use the UKCA mark until **30 June 2023**), but they may need to comply with additional registration requirements and other operational challenges. Manufacturers must ensure that the correct rules apply to each type of product they sell.

4.4 UK Declaration of Conformity Certificate

Products lawfully bearing a UKCA mark must have a UK Declaration of Conformity Certificate, which must be made available to market surveillance authorities on request. The information required in this document will be largely the same as that currently required in an EU Declaration of Conformity.[17] Generally, it should include:

- the manufacturer's name and full business address (or that of an authorised representative);
- the product's serial number, model or type identification;
- a statement or declaration by the manufacturer taking full responsibility for the product's compliance;
- the details of the approved body which carried out the conformity assessment procedure (if applicable);

[17] If a business has a Certificate of Conformity from a UK-based notified body and has applied a CE mark to their product on that basis, and the business wants to continue to sell that product on the EU market, it will need to apply a new certificate from an EU-based notified body (as UK bodies will not be recognised after 31 December 2021 (unless there is a significant change to the current arrangements)

- the relevant legislation with which the product complies;
- the manufacturer's name and signature;
- the date the declaration was issued;
- and any supplementary information (if applicable).

From **1 January 2021** the UK standards used to assess products in order to award a UK Declaration of Conformity Certificate 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 BSI (the UK's national standards body).

4.5 Documentation requirement

There is a requirement on a business to keep documentation to demonstrate that its product conforms with all regulations. This requirement will remain under the new UKCA marking scheme.

As now, the information that must be maintained will vary depending on the relevant product legislation. In general, a business must keep records of:

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

This documentation must be kept in the form of a technical file 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 the product conforms with the statutory requirements.

4.6 Authorised representatives

From **1 January 2021**, authorised representatives (and responsible persons) based in the EU will no longer be recognised in Great Britain. Therefore, manufacturers using an authorised representative in respect of products placed on the Great Britain market will need to ensure that person is based in the UK.

It is also the case that from **1 January 2021**, authorised representatives (and responsible persons) based in the Great Britain will no longer be recognised by the EU. This means that UK businesses that will have to appoint an authorised representative in the EU, EEA or Northern Ireland.

4.7 Enhanced responsibilities of UK distributors

Government guidance states that manufacturers' legal obligations will remain largely unchanged from 1 January 2021. However, this is not the case for UK distributors.

From 1 January 2020, UK products placed on the EU market will be considered imports into the EU. Distributors of such products (bearing CE marking) will be treated as importers for these purposes; this was not the case previously. The obligations of importers and distributors in the EU are set out in the European Commission's Blue Guide on EU product rules.[18][19]

EU-based distributors of products from the UK will, after 31 December 2020, be required to verify that:

- the goods are labelled with details of their address and either the manufacturer's details or those of its EU, EEA or Northern Ireland representative;
- the correct conformity assessment procedures have been carried out and the goods have the correct conformity markings;
- the manufacturer has drawn up the correct technical documentation and complied with the applicable labelling requirements;
- they maintain a copy of the "declaration of conformity" for a period of 10 years and goods conform with the relevant essential requirements.

The flip side is that a UK distributor will become an importer where it brings EU goods into the UK and places them on the market in Great Britain (England, wales and Scotland but not Northern Ireland). The same requirements (as outlined above) will apply except that, until 31 December 2022, it will be possible to provide contact details on the accompanying documentation instead of on the good itself.

[18] The Blue Guide, first published in 2000, explains how to implement EU product legislation based on the New Approach, and subsequently the New Legislative Framework for the marketing of products.

[19] The European Commission has begun preparations to update the Blue Guide on EU product rules, stakeholders were invited to summit suggestions about issues to include in the updated version (the consultation closed on 15 January 2020)

5. Detail of the new UKNI marking scheme

5.1 When to use the new UKNI mark?

From 1 January 2o21, a manufacturer will need to use the UKNI marking if **all** of the following apply:

- they are placing certain goods (mostly those goods currently subject to the CE marking) on the Northern Ireland market;
- the goods require mandatory third-party conformity assessment;
- they intend to use a UK body to carry out those conformity assessments.

A manufacturer will **not** be able to use the UKNI marking if **either** of the following apply:

- they are placing goods on the market in the EU
- they are planning to use an EU body to carry out conformity assessments.

It is important to note that if manufacturers based in Northern Ireland (or their authorised representative) currently mark their goods on the basis of a supplier's "Declaration of Conformity", they will not need to make any changes. Their goods will continue to be valid on the UK and EU markets using the relevant conformity markings.

5.2 Technical requirements

As already mentioned, the UKNI marking cannot be placed on products unless there is a specific requirement to do so in the legislation. The UKNI marking must accompany another conformity marking; it never appears on a product alone.

The UKNI mark must only be placed on a product by the manufacturer (or their authorised representative). When attaching the UKNI mark to accompany another conformity marking, the manufacturer takes full responsibility for their product's conformity with the requirements of the relevant legislation.

In most cases, the manufacturer must apply the UKNI mark to the product itself or to the packaging. In some cases, it may be placed on the manuals or on other supporting documents. This will vary depending on the specific regulations that apply to the product.

The manufacturer must not place any marking or sign that may misconstrue the meaning or form of the UKNI marking to third parties. In addition, the manufacturer must not attach other markings on the product which affect the visibility, legibility or meaning of the UKNI mark.

5.3 What products will the new UKNI mark apply to?

As outlined in **Box 7** below, the list of products subject to the new UKNI marking closely mirrors the position for UKCA marking.

Box 7: What products will the new UKNI mark apply to?

The list is as follows:

- aerosols
- appliances burning gaseous fuels
- cableway installations designed to carry persons
- certain hazardous substances in electrical and electronic equipment
- construction products
- eco-design of energy related products
- electromagnetic compatibility
- equipment and protective systems intended for use in potentially explosive atmospheres
- hot-water boilers
- household refrigerators and freezers
- lifts
- low voltage electrical equipment
- machinery
- measuring instruments
- noise emission in the environment
- non-automatic weighing instruments
- personal protective equipment
- pressure equipment
- pyrotechnics
- radio and telecommunications terminal equipment
- recreational craft and personal watercraft
- safety of toys
- simple pressure vessels

Three product categories – medical devices, rail interoperability, and civil explosives - are covered by the UKNI marking but are also subject to special rules.

5.4 Declaration of Conformity Certificate

The EU Declaration of Conformity is a document which must be drawn up for most products lawfully bearing a CE marking, whether it is accompanied by a UKNI marking or not.

The information required on the Declaration of Conformity will be the same as what has been required before 1 January 2021. Specifically, the manufacturer or their authorised representative (where allowed for in the legislation), must:

- declare that the product is in conformity with the relevant regulatory requirements applicable to the specific product;
- make sure the document has the name and address of the manufacturer (or their authorised representative) together with

information about the product and the conformity assessment body (where relevant).

The EU Declaration of Conformity should be available to enforcement authorities on request.

5.5 Documentation requirement

The manufacturer, their authorised representative (where allowed for in the relevant legislation) or importer, must keep certain documentation to demonstrate that their product conforms with the regulatory requirements. The documentation will vary depending on the specific legislation relevant to the product. However, general records must be kept of:

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

This information, which must be kept in the form of a technical file, must be kept for up to 10 years after the product is placed on the market. As in the rest of Great Britain, this technical file must be made available on request to an enforcement body.

6. Next steps

How the UK will proceed from the 1 January 2021 will depend on whether an UK-EU trade agreement is achieved in the final weeks of the transition period and, if so, the terms of that agreement. For example, a trade agreement might include a comprehensive system of mutual recognition of product standards and conformity marks. However, the Government has indicated that it would be sensible for UK manufacturers to work on the assumption that there will be no change to the new regulatory regime outlined in the most recent guidance and that this will apply from 1 January 2021.[20]

[20] Department for Business, Energy and Industrial Strategy, "Using the UKCA mark from 1 January 2021", 1 September 2020 [online] (accessed 1 December 2020)

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