

### SHEP Understanding and Using the New UKCA & UKNI Marks

Q&A

### **Q**: Will there be a different procedure if the product falls under 3rd party certification as against self-certification?

The technical requirements for third-party assessment and self-declaration for UKCA marking are as they were for CE marking. The circumstances in which goods can be UKCA marked based on self-declaration are the same as those for CE marking. Whereas, if the product requires a third-party assessment, they will now need to be completed by a UK recognised Approved Body in order to be UKCA marked.

### Q: In the case of self-declaration, how can we present this on our certificate? So basically can a self-declaration be issued without having an approved body assess it?

If a product is subject to self-declaration, then businesses can choose to support it with a test report by a test house or accredited laboratory, this will be permitted for UKCA marking in the same circumstances as for CE marking. Businesses can self-declare without the approval of UK recognised approved body, where it's permitted by the product specific legislation. The details of the declaration of conformity (and the required contents of the technical file) are the same as for CE marking but instead of referencing EU legislation it must reference the relevant UK legislation.

# Q: So we can use a CE mark and UKCA mark on the same product, as long as we can prove compliance to both, can that product then be sold into the NI market if no UKNI mark is required?

Businesses can place the UKCA and CE marking on the same product if it is destined for both the EU and the GB markets so long as the product meets the relevant regulatory requirements for both markets. However, the UKCA marking cannot be used for goods placed on the Northern Ireland market. For the NI market, you can continue to apply the CE marking if you use an EU notified body or self-declare to assess the products. If you choose to assess the products through a UK recognised approved body, then businesses must use the UKNI+CE marking.

### Q: For UKNI marking, what declaration do you use?

The requirements for the Declaration of Conformity (DoC) for the UKNI marking remain the same as the DoC for the CE marking. See BSIF's helpful document <u>https://www.bsif.co.uk/wp-content/uploads/2021/02/ls-it-genuine.pdf</u> for more information.

## Q: If we are selling a product made in the UK, that doesn't need a notified body, can we sell into NI and EU without an EU representative?

If your goods are being sold from GB into the EU or NI via an EU or NI based distributor then that distributor will be considered an importer and their address must appear on the product unless you have assigned another EU or NI based operator to act as the importer in which case their address will be required. From 16 July 2021 you will need to appoint an authorised representative based in the EU, EEA or NI if you sell goods into the EU without



using an importer or fulfilment service provider. For example, if you sell online and ship directly to the end user.

## Q: Under the energy products labelling, i noticed the label is changing to include UK flag

For the GB market, manufacturers are required to display the UK energy label, while for the NI and EU market, they are required to display the EU energy label. The UK flag must be displayed on all energy labels in the GB market from 1 January 2021.

Q: I sent an email to BEIS back in December with regards to BASEC (UKCA approved governing body for cable testing) with some questions, which I still have not had a response too - despite having an automated email back stating it would be answered within 10 days. Who would be best to contact to get a response?

Sincere apologies, please contact goodsregulation@beis.gov.uk for any queries.

### Q: When you say "place on the market" do you mean launched into the market place? Or do you mean simply sold on the market (so already designed and released products, sold next

Placing on the market is defined as a fully manufactured (individual) good that is 'placed on the market' when a written or verbal agreement (or offer of an agreement) to transfer ownership or possession or other property rights in the product that is exchanged. This does not require physical transfer of the goods. See <u>https://www.gov.uk/guidance/placing-manufactured-goods-on-the-market-in-great-britain</u>

# Q: We place processed steel onto market, globally. We have previously had our CE systems audited by a UK 'notified' body. This will become UKCA marking as we know. This is a UK based 'notified body'. After 01/01/21 we now have the requirement to have an additional assessment carried out by an EU notified body in order to supply products into the EU. Will there be an agreement in place to remove the requirement for two separate audits for both CE and UKCA marking, or will we need to two separate audits going forwards indefinitely?

Without a mutual recognition agreement, where third party assessment is required you will need to plan on having a certificate of conformity issued by a UK-recognised body to sell your good in GB. Whereas to place goods on the EU market, you will need to plan on having a certificate of conformity issued by an EU notified body, this will not include UK approved bodies. Unless the two bodies are able to set up some sort of arrangement between them within the boundaries of what is acceptable under UK and EU legislation, this will likely mean e.g., two sets of audit requirements. The UK proposed a mutual recognition agreement in recent negotiations with the EU, but the EU did not agree to this.

### Q: Is there any stipulation where you need to be based to sign the D of C for UKCA, as previously you needed to be based in the EEA for CE.

The Declaration of Conformity is the responsibility of the manufacturer and can be signed wherever they are located. Or an Authorised Representative may also stand in for the



manufacturer and sign in their place. For the GB market, only UK-based ARs are recognised.

### Q: What's an accompanying document? Is there a definition?

There is no set definition of an accompanying document. For the UKCA marking (i.e., during the 2 year period during which UKCA marking can appear on an accompanying document) it can be on any document that accompanied the product until it meets its end user. For the purposes of putting an importer address on accompanying documentation, please see the detailed guidance published by the Office for Product Safety and Standards: <a href="https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\_da\_ta/file/957552/Guide-to-ppe-regulations-2018-tp-version-3.pdf">https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\_da\_ta/file/957552/Guide-to-ppe-regulations-2018-tp-version-3.pdf</a>

# Q: We are a GB-based IT firm who place goods on the wider UK and EU markets. We currently self-declare CE. I assume we will need to move to the UKCA marking? Can we use this same UKCA marking when place goods on the NI or EU markets as well? It would be quite painful to have to use a different marking depending on the destination on the goods sold.

The UKCA marking is not recognised on the EU market, and products currently requiring a CE marking for sale in the EU will continue to need a CE mark. The UKCA marking shows compliance to the GB's new domestic regime, indicating conformity for the GB market. Products that are destined for both the EU and GB market can be dual marked with the UKCA marking and the CE marking if they meet the regulatory compliance for both markets.

For Northern Ireland: The UKCA marking cannot be used for goods placed on the Northern Ireland market. If you currently apply the CE marking to your good on the basis of self-declaration, as required by the relevant product legislation you can continue to do this so.

## Q: After Jan 2022, does CE mark product have to be recalled and replaced with UKCA mark from the market?

If the goods were placed on the market before 31<sup>st</sup> December 2022, these goods will not need to be recertificated as they can continue to circulate on the market until they reach the end user.

### Q: Would there be difference in free sale certificate, for UKCA and UKNI mark?

Please could you email <u>goods.regualtion@beis.gov.uk</u> so we can understand this Q further in order to provide a response.

# Q: As a PPE consumer, if traveling employees use PPE in GB, CE and NI jurisdictions, does the PPE need to have CE, UKCA and UKNI product markings? eg. safety footwear, hard hats, ear defenders, safety glasses, filtering facepieces, etc.

No, if product is to be placed on the market in GB, it will require a UKCA marking. For the EU market, it will require the CE marking or CE+UKCA marking if placed on both markets. For the Northern Ireland market, the CE marking will be recognised in NI for the foreseeable future.



## Q: If we sell EU origin products into the GB to several "importers", can we identify one GB importer name and address only in the product documentation?

Yes – although that importer would need to assume legal responsibility for all products being "imported" including those they are not physically responsible for bringing into GB.

## Q: Product documentation definition, please: invoices to GB importer or instruction manual?

There is no set definition of an accompanying document. For the UKCA marking (i.e. during the 2-year period during which UKCA marking can appear on an accompanying document) it can be any document that accompanied the product until it meets its end user. For the purposes of putting an importer address on accompanying documentation, please see the detailed guidance published by the Office for Product Safety and Standards: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\_da ta/file/957552/Guide-to-ppe-regulations-2018-tp-version-3.pdf

# Q: We are about to enter the EU market with a New Industrial Air compressor. This is covered under the Machinery Directive and we will be self-certifying. Is there anything else we need to consider?

We are not able to provide advice on your specific circumstances and would encourage you to seek external advice, such as from your solicitor or trade association, if needed.

## Q: Can goods be placed into NI with the CE mark only where the notified body is in the EU?

Yes, a UK Approved Body cannot give CE approval for NI, only an EU notified body. The CE marking will be only valid for the EU market and the NI market.

### Q: Does the 2019/1012 Regulation only apply to products sold on-line?

If your query is regarding the 2019/1020 Regulation, please contact <u>goods.regulation@beis.gov.uk</u> so we can provide further advice.

Q: We produce capital equipment, which consists of multiple purchased components that are currently CE marked. When supplying to the UK will all components have to be UKCA marked or can the CE component still be used, especially in the short term where currently the two standards are identical.

As the signatory for the final assembly can an assumption be made that if the component is CE compliant it will meet the needs of the UKCA standards using the evidence that the component is produced to a directly comparable standard?

Where there is a requirement in the legislation for components to be individually conformity marked, manufacturers are required to affix the UKCA marking to individual components as well as the final product. However, if the components are placed on the UK market before the end of the transition period, they can circulate on the UK market until they meet their end



user. This means that the components can be incorporated into a final product with the UKCA marking if they were placed on the market whilst this was permitted.

### Q: After Jan 2022, can CE marked components be used in a UKCA marked assembly, placed on the market after Jan 22?

Yes, the overall assembly can be placed on the GB market after 1 January 2022 (bearing the UKCA marking) and can include CE-marked components but only if those components were placed on the GB market before 31 December 2021. If components are placed on the GB market after 1 January 2022, they will require the UKCA marking.

Until 1 January 2023, you have the option to affix the UKCA marking on a label affixed to the product or on an accompanying document.

A fully manufactured (individual) good is 'placed on the market' when a written or verbal agreement (or offer of an agreement) to transfer ownership or possession or other property rights in the product is exchanged. This does not require physical transfer of the good.

### Q: Will all legislation which requires CE marking on different types of product be updated prior to 1st January 2022 to require UKCA marking, e.g. Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016, and if not, what

Please note that UK product safety and metrology has been published, please view product specific guidance, here: <u>https://www.gov.uk/guidance/product-safety-for-businesses-a-to-z-of-industry-guidance</u>.

# Q: We supply CNC Machine tools into UK and Europe. Historically we have issued CE certificates from our UK office. Are we legally compliant if we set up a "Registered branch office" within the EU to enable us to continue to issue CE certificates for the EU?

Any mandatory conformity assessment for the EU market needs to be carried out by an EUrecognised conformity assessment body. This includes both EU based bodies and bodies in countries with which the EU has concluded a mutual recognition agreement. UK conformity assessment bodies cannot carry out mandatory conformity assessment for products being placed on the EU market. For the latest updates on the EU's requirements please consult the <u>European Commission's website</u>.

If a good is subject to self-declaration of conformity, a declaration of conformity for CE marking can be issued by an entity not established in the EU (although depending on mode of distribution an EU based importer address may be required on the product).

### Q: If we are buying a piece of process plant from an EU based manufacturer, should it be CE or UKCA marked?

UK businesses can continue to import CE marked goods until 1<sup>st</sup> January 2022 in most cases. But from 1<sup>st</sup> January 2023, products that are to be placed on the GB market will need to have the UKCA marking.



Q: Will BS EN 1090-2 (Execution of steel structures and aluminium structures) still apply following the implementation of UKCA marking? The standard requires the ce marking of fabricated steelwork structures. If not is the standard to be withdrawn or updated?

Our understanding is that CE and UKCA marking for Structural Steel and Aluminium products can only be to EN 1090-1 standard – that is the harmonised European standard and designated standard.

EN1090-2 is referred to in EN 1090-1 – particularly for tolerances and EXEC classes but EN 1090-2 is not a cited harmonised European standard or designated standard. But it will be the version that the steel producer/fabricator needs to consider in their work when constructing steel structures.

Any references to EU law in designated standards should be read as applying to the legislation for GB in the same way, subject to any restrictions or points made in the relevant notice of publication.

Any contracts for fabricated structural steelwork for buildings should include the National Structural Steelwork Specification (NSSS) for Building Construction (7thEdition), which incorporate the obligations of BS EN 1090-1 and BS EN 1090-2 on the steelwork contractor.

### Q: The word 'most' has been used for goods, where do we find exact description of items?

A: Please see the list of products that are covered the UKCA marking, please visit: <u>https://www.gov.uk/guidance/using-the-ukca-marking#more-information</u>.

### Q: Why does an item CE marked become disqualified for EU market if additionally, it bears UKNI?

The UKNI marking has a very specific purpose for products placed on the market in Northern Ireland under the terms of the Northern Ireland Protocol (part of the UK-EU Withdrawal Agreement). Manufacturers only need to apply it if their products are subject to mandatory third-party conformity assessment by a Notified Body and this Notified Body is based in the UK.

- You need to use the UKNI marking (alongside the CE marking) if all of the following apply:
  - you are placing certain goods (mostly those goods subject to the CE marking) on the Northern Ireland market
  - · your goods require mandatory third-party conformity assessment.
  - you are planning to use a UK body to carry out those conformity assessments.
- You are not able to use the UKNI marking if either of the following apply:
  - you are placing goods on the market in the EU.
  - · you are planning to use an EU body to carry out conformity assessments.



### Q: We are an agricultural business that 'buys' a large amount of machinery that is bespoke built for us and imported to us in the UK. Am I correct in thinking from Benedict's presentation we would now need to request them to have the machinery marked in line with UKCA marking?

Yes, but to help businesses with the transition, most CE marked goods can continue to be placed on the UK market for 12 months from the end of the transition period (until 1 January 2022). Until 1 January 2023, for most CE marked goods, there will be the option to affix the UKCA marking on a label affixed to the product or on an accompanying document.

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

# Q: Can we purchase material from the EU, work on it and sell it as UKCA in the UK but show traceability of the original material through the CE marking QA systems. ie, does the UKCA recognise CE marking products?

Products that are to be placed on the GB market from 1 January 2022 will need to have a UKCA marking, The CE marking will no longer be recognised in the GB market, but the UKCA marking will be demonstration conformity for the GB market.

# Q: We have several major projects underway (for which contracts were signed prior to Brexit) which will incorporate multiple CE marked components manufactured across multiple global locations, many complexes, where the final assembly and conformity assessment will not be completed until after 1 January 2022. Can the final installation be UKCA marked?

The overall assembly can be placed on the GB market after 1 January 2022 (bearing the UKCA marking) and can include CE-marked components but only if those components were placed on the GB market before 31 December 2021. If components are placed on the GB market after 1 January 2022, they will require the UKCA marking.

Until 1 January 2023, you have the option to affix the UKCA marking on a label affixed to the product or on an accompanying document.

A fully manufactured (individual) good is 'placed on the market' when a written or verbal agreement (or offer of an agreement) to transfer ownership or possession or other property rights in the product is exchanged. This does not require physical transfer of the good.

# Q: We are a wholly owned subsidiary of a multisite EU based company. Our products are manufactured in the EU and self-certified for CE certification. We assume we can amend our declaration of conformity to reflect and be referenced to the new UKCA and add this.

Yes, if you currently self-certify for the CE marking, you can continue to do so for the UKCA marking.



## Q: Does the certificate of declaration have to be signed by someone residing in the UK or are the existing signatories acceptable?

No, manufacturers can sign the DoC regardless of wherever they are located.

# Q: If a product has been previously CE marked by a UK Notified Body does this now need a complete full assessment or is it just administration and issue of a new Declaration of Conformity?

The latest UK Government guidance on this can be found here: https://www.gov.uk/guidance/uk-conformity-assessment.

## **Q**: Am I being too simplistic when considering that the relevant assessments for the multiple

Yes, the required conformity assessment procedures and relevant standards for UKCA marking are currently the same as for CE marking.

## Q: If I have PPE with EU marking and not been used until or after January 2022, should I return these to the supplier?

No, they were fine when placed upon the market so fine to continue.

## Q: We import some items with CE Marking on them which then go on to our customers. Are we responsible for organising the UKCA marking that is required on the items we import?

If you are an importer, who will bring third party products onto the GB market, then you must ensure that the manufacturer has fulfilled their obligations, and the product carries the correct marking (UKCA marking, although CE marking is acceptable until 1 January 2022).

# Q: If you have a slow-moving item in stock with a CE mark that could still be there after December 2021, do you have to find someone to UKCA mark it in order to sell it on?

CE marked goods placed on the GB market until 31 Dec 2021 can continue to circulate on the UK market until they reach their end user and will not require recertification.

# Q: Policing of this under CE rules was variable, how are you going to ensure compliance for this process. Manufacturers of skid units for petro chem / gas installations and assemblies do not understand when a DoC is required and if you get one, they never cover all relevant directives. Will UK or EU directives be referenced on a DoC?

The government takes the issues of product safety seriously and is committed to ensuring that only safe products are placed on the UK market now and in the future.

Our legislation ensures that producers have a responsibility to only put safe and compliant products on the market – this has not changed, as ensuring the UK retains an effective product safety regime is a priority.

Following 1 January 2021, the requirements that products must meet that are based on EU law have been retained through the European Union (Withdrawal) Act. This means that



since day 1 after the end of the transition period, goods are only able to be sold on the UK market if they meet the same safety requirements as they do now.

As for the second aspect of the question, businesses now must refer to UK regulation on the DoC rather than EU directives.

# Q: What if there is no UK approved body capable of carrying out the necessary testing? Or what if there is insufficient test house capacity to conduct the necessary test work before the 31-12-21 deadline?

The types of conformity assessment required for a good to be compliant under the UK regulatory regime will be the same as required under the EU rules. A certificate of conformity issued by a UK-based notified body before 1 January 2021 will continue to be recognised after this date for the purposes of UKCA marking.

We have been engaging further with both conformity assessment bodies and manufacturers to ensure that the process of acquiring new certificates of conformity where needed is as smooth as possible. Ideally this would be without the need for retesting where possible. The Withdrawal Agreement means that notified bodies should share information relating to conformity assessments with other bodies were requested by the manufacturer, which is intended to help facilitate this.

# Q: If a model of a product is brought to market before January 2021 and has a CE mark, did I understand correctly that model can be sold for its lifecycle with only the CE mark, or does that only apply to the individual items brought in the GB before Jan 2022, and after that date the items of that same model will then need UKCA?

Products that are placed on the market up until 31 December 2021 can continue to circulate on the market and will not require recertification. However, from 1 January 2023, the UKCA marking must, in most cases, be affixed directly to the product, unless specified in the product specific legalisation otherwise. Businesses should start building this into your design process ready for this date as soon as possible.

## Q: What will happen to the EU guidelines on the different directives and the EU blueguide? Will these interpretation supports be transferred to the UK?

We are currently exploring the introduction of a UK equivalent to the Blue Guide. For the time being, there are no plans to adopt different interpretations to those in the Blue Guide. <u>https://ec.europa.eu/growth/content/%E2%80%98blue-guide%E2%80%99-implementation-eu-product-rules-0\_en</u>.

## Q: Can a UKCA marked device on market in UK, if not CE marked, be taken over on ferry to Ireland for temporary use (say for weekend) in a professional context?

The key issues here to consider is whether if your good is/was placed on the market. A good is 'placed on the market' when a written or verbal agreement (or offer of an agreement) to transfer ownership or possession or other rights in the product. This refers to each individual good, not to a type of good and does not require physical transfer of the good.

If your products are CE marked with certificates from an EU body, you can continue to place them on the GB market with only the CE mark until 1 January 2022, even if they are held in



a distribution hub (no matter where that is based). From 1 January 2022, they will have to be UKCA marked, even if they are held in a distribution hub (regardless of location).

# Q: For EU medical devices directive, as transcribed into UK medical devices regulations. Is there a "consolidated version" of the UK MDR incorporating amendments to make clear any differences to EU MDD?

<u>The Medical Devices Regulations 2002</u> were amended by the <u>Medical Devices (Amendment etc.) (EU Exit) Regulations 2019</u> and the <u>Medical Devices (Amendment etc.) (EU Exit)</u> <u>Regulations 2020</u> and these should all be read together.

Unfortunately, MHRA does not own a consolidated version of the legislation, and this needs to be made by the legislation.gov.uk editorial team.

There are legal firms that provide consolidated versions of legislation, which you can purchase.

## Q: Regardless of when a product is based on the market, do all applicable goods from 1st Jan 2023 need the UKCA marking regardless of when placed on the market?

Yes, products that require the UKCA marking cannot be placed on the GB market without it (other than where the CE marking is being used before 1 January 2022).

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

# Q: I CE Mark equipment for my organisation. The sole purpose of the equipment is for use by our own employees to provide a service to our customers. (Not for sale). Will CE Marking still be required? Will I still be able to carry out the CE Marking while being based in the UK?

In general, if a good requires a CE marking, it will be subject to UKCA marking. If it does not require CE marking it will not require UKCA marking. If you self-declare CE marking, then you can do the same for the UKCA marking.

# Q: I believe BSI membership of CEN is only confirmed until the end of 2021 after which BSI continued membership and contribution to standardisation Norms is subject to determination by CEN. How will this affect CE, UKCA and UKNI marking and is there a default position should CEN not wish to engage further with BSI?

The requirements for affixing the UKCA marking mirror those for the CE marking. This includes both the essential requirements and the harmonised standards that are used to give presumption of conformity. Businesses will be able to use these 'designated standards' to provide presumption of conformity with GB law. Designated standards will be prefixed "BS", "EN", "EN ISO" or "EN IEC.

### Q: For Annex IV machinery imported to GB, does certification have to be carried out by a GB Approved Body or can it still be an EU Notified Body?



From 1<sup>st</sup> January 2022, the certification will need to be carried out by a UK recognised Approved body.

Q: We are selling milling equipment to pharmaceutical companies who are having plants all over the world. We are currently using CE marking and they are free to move their machinery between plants as they wish. If they decide to move machinery originally sold for them to use in UK to an EU site, do we have to use both markings at point of sell or the UKCA will suffice?

This question refers to the movement of second-handed machinery. When transferring these goods, As the user of second-hand machinery, you have a duty to make sure it is:

- safe when put into use;
- suitable for the selected work; and
- maintained in a safe condition.

If second-hand machinery has been subject to important changes, overhauling its original performance, purpose, or type, then this machinery is considered as a new product. Therefore, in order for it to be placed on the GB market it will need to comply with the new GB regulatory requirements, including the requirement for UKCA marking (noting that for a limited time period until 1 Jan 22, goods lawfully CE marked and certified by an EU body may be placed on the GB market).

## Q: Where does a product sit in relation to Rail Interoperability and also Construction and Use regs? We run Road Rail Machines that obviously are dual purpose so sit in both areas.

For the transition arrangements regarding products covered by the Rail Interoperability legislation see the following link : https://www.gov.uk/guidance/railways-interoperability-eu-exit-regulations The Road Vehicles (Construction and Use) Regulations 6 on design, manufacture, maintenance, construction and use of motor vehicles and trailers used by road transport operators, amongst others fall to the department for Transport (DfT) policy. See link to updated 2020 regulations

https://www.legislation.gov.uk/all?title=road%20vehicles%20construction%20and%20use

## **Q**: Is there a matrix showing the comparison of regulations and their applicable harmonised standards that apply?

Please see the published guidance on Designated standards: <u>https://www.gov.uk/guidance/designated-standards#conformity-assessment-and-management-systems</u>.

### Q: Are UK still allowed to create CE declarations for Europe sales?

UK Approved bodies cannot no, they can approve for the UKNI and UKCA, but not CE.

Where a product is being self-declared, a UK manufacturer can draw up an EU Declaration of Conformity, but where a third-party certificate of conformity is required this will need to be issued by an EU recognised body.



## Q: Will forcing manufacturers of components to UKCA mark components limit the availability of components to the UK?

To help businesses adjust to the changes, until 1 January 2023, for most goods currently subject to the CE mark, you have the option to affix the UKCA marking on a label affixed to the product or on an accompanying document. From 1st January 2023, where there is a requirement in the legislation for components to be individually conformity marked, manufacturers are required to affix the UKCA marking to individual components as well as the final product.

## Q: If I have CE approved PPE when do I need to produce UKCA approved PPE? Can I still use CE PPE and until what date?

A: You can begin now, but by end of Dec 21 you must produce all new PPE for the UK with UKCA marking. PPE produced before and placed on the market before that date can continue to be sold.

# Q: We are a Middlesex based daughter company of a Swiss manufacturer. We distribute our company's products throughout Eng/Wal/Sco/NI and Rep of me. Will we need to hold in our stock 3 lots of each item having CE, UKCA and UKNI marks?

If you are selling GB – UKCA. If you're selling EU – CE. If you are selling NI – CE will suffice if you self-declare conformity or use an EU notified body for your conformity assessment.

# Q: Typically, we procure packages of equipment that are CE marked. Under current legislation the Certificate of Conformity list all the relevant directives - e.g. Pressure Equipment Directive, Machinery Directives, ATEX etc. Is this the same for UKCA?

Yes, the technical requirements for Pressure Equipment Directive, Machinery Directives, ATEX etc have remained same. Please see the corresponding UK legislation: <u>https://www.gov.uk/guidance/placing-manufactured-goods-on-the-market-in-great-britain#more-information</u>.

# Q: Also, had a quick look at the pressure equipment specified standards from the link on the slides however noted that there is no reference to PD5500 (only EN 13445) - is the list provided full and fixed?

The designated standards lists are full and correct. Immediately after the transition period ended, all harmonised standards that give a presumption of conformity to EU law became 'designated standards' by the references published on GOV.UK. With regard to the PD5500 (Specification for unfired pressure vessels) this is not referenced as a designated standard; whilst the document is available on the BSI website this should not be regarded as a British Standard.

The Government is working with BSI to ensure we have the necessary information for the management of designated of standards. This will include BSI informing us when new or revised European harmonised standards can be considered for designation.



## Q: With regards to machinery already built and CE marked, will we need to add UKCA and UKNI markings to them before they leave the manufacturer?

After Dec 2021 yes, but you can use sticky labels with UKCA until end 2022. After this all products placed on the GB market must be UKCA or dual marked if sold in both markets.

Fully manufactured CE marked goods can continue to be placed on the market until 31 December 2021 However, to help businesses adjust to transitional measures, until 1 January 2023 for most CE marked goods, there will be the option to affix the UKCA marking on a label affixed to the product or on an accompanying document.

From 1 January 2023, the UKCA marking must, in most cases, be affixed directly to the product.

For Northern Ireland market, you can continue to use CE marking.

Q: If a complex assembly of pressure equipment is placed on the UK market after 31 December 2021, and therefore is required to be UKCA-marked in compliance with PER; will the UK authorities accept the incorporation of CE-marked components and materials in such assemblies, if UKCA-marked components and materials were not available at the time of purchase?

Yes, the overall assembly can be placed on the GB market after 1 January 2022 (bearing the UKCA marking) and can include CE-marked components but only if those components were placed on the GB market before 31 December 2021. If components are placed on the GB market after 1 January 2022, they will require the UKCA marking.

### Q: If we are buying a machine from the EU into the UK who will now hold the technical file?

A: The Manufacturer will be responsible for holding the technical file.

Q: "We produce capital equipment, which consists of multiple purchased components that are currently CE marked. When supplying to the UK will all components have to be UKCA marked or can CE component still be used, especially in the short term where currently the two standards are identical.

# As the signatory for the final assembly can an assumption be made that if the component is CE compliant it will meet the needs of the UKCA standards using the evidence that the component is produced to a directly comparable standard?

Yes, as along as the CE marked components were placed on the market before 31 December 2022, then the final product can be placed on the market bearing UKCA mark from 1 January 2023.



## Q: What about the standards has lay behind CE. eg the machinery directive (2006/42/EC). These are EU standards, what does UKCA use?

As noted above, all harmonised standards that give a presumption of conformity to EU law became 'designated standards' by the references published on GOV.UK.

Designated standards are prefixed "BS", "EN", "EN ISO" or "EN IEC". The "EN" prefix indicates that the standard has been adopted by a European standardising body. Where the designated standard specified in the notice of publication is prefixed "EN" it is acceptable to reference this version in technical documentation, or a version of the same standard with a national prefix. This is because European standards are adopted identically by the 34 national members of CEN and CENELEC.

### Q: Will the UKCA mark be recognised outside of the UK?

No, the UKCA marking is recognised as demonstrating compliance with UK regulations for products being placed on the Great British market. The UKCA marking alone will not be recognised outside GB. For placing goods on the EU market, businesses will continue to conformity mark their product with a CE mark.

If you are placing goods on both the GB and EU market you can attach both UKCA+CE marking on the same product, as long as the product meets the relevant regulatory requirements for both markets.

### Q: We import product from our parent company in Germany and hold them in stock and then supply them to both UK and Ireland markets, North & South. Can we mark with both UKCA marking and CE marking, or can goods destined for Ireland only have the CE Marking?

As above, if you are placing goods on both the GB and EU market you can attach both UKCA+CE marking on the same product, as long as the product meets the relevant regulatory requirements for both markets.

### Q: Is there any possibility of mutual recognition between the different Marks?

The UK proposed a mutual recognition agreement which would have covered recognition of conformity assessment (but not markings) in recent negotiations with the EU, but the EU did not agree to this.

### Q: If an EU CE marked good, is imported into the UK by an NI market, what conformity documentation is required?

If the CE marked goods are destined for the Northern Ireland market only, you can continue to use an EU notified body or self-declare to assess the products. You will therefore need to complete the EU Declaration of Conformity.

## Q: For steel being imported into UK for domestic consumption does it need to be recertified by a testing house in the UK?



For steel being imported into GB testing any conformity assessment requirements under this standard will need to be carried out by a UK approved body, your approved body can advise if recertification is required. Steel being imported into NI can use UK approved body if the manufacturer wants to use the CE UKNI mark or an EU notified body, if they want to use the CE mark and place the product on the NI and EU markets.

I have attached the questions for context, please kindly review to see if there is anything I have missed.

### Q: What is the transition period for UKCA marking structural steel?

CE marking will continue to be recognised in both the UK markets of GB and NI throughout 2021, but from 1 January 2022 CE marking will no longer be acceptable in GB. Please note that in relation to the non-recognition of the CE mark for construction products, our guidance states that Businesses must prepare for the end of recognition of the CE mark in GB and affix the UK marking using a UK-recognised 'approved body'. Our intention is to end recognition of the CE mark by 1 January 2022 and to introduce new legislation to do that in due course".

With regard to placing CE marked good on the UK market this year, our guidance states that "Under the terms of the Withdrawal Agreement, goods lawfully marked with the CE mark and placed on the EU market before the end of the transition period can continue to circulate until they reach their end user, whether they are in the UK or the EU.

This includes requirements that they:

- •are covered by a harmonised European standard, which is the same as a UK designated standard (as noted above)
- •are affixed with CE marking
- •are accompanied by a manufacturer's declaration of performance
- •have been assessed by an EU-recognised notified body, where third party assessment is required.

It will be up to any economic operator, relying on this provision, to prove that the goods were placed on the market before the end of the transition period. "

Therefore, retailers should continue to accept CE marked goods if those goods are placed on the market before and up to the end of the transition period. Retailers holding stock of CE marked goods marked can continue to sell those products even after the end of the transition period, until that stock is finished.

### Q: Can a certified UK notify body in UK be certified notify body for EU?

If it has an EU based identity separate from its UK Approved body status, then yes. UK based bodies cannot directly become EU notified bodies and EU based bodies cannot



directly become UK approved bodies, although it may be possible for UK and EU bodies to establish arrangements that allow e.g., a UK body to conduct testing to support e.g. CE certification issued by an EU based entity.

## Q: I am looking for some advice on labelling of refrigeration pipework. Is it mandatory/statutory or optional?

. It would only be the copper joints and fittings used that would require CE/UKCA marking if they were manufactured to EN 1057 standard. The copper pipework for use in refrigerant piping itself isn't manufactured to a designated standard.

## Questions answered during the Q&A section in the webinar, the recording of which can be accessed here:

https://attendee.gotowebinar.com/recording/5268216919249472779

Q: If you have multiple products that are currently assessed to the same EU standards by EU NoBo, can these be approved en-masse, or do they need individual recertification to UKCA?

A: Provided in webinar

Q: We are placing the UK importer address on the manual. Are digital manuals accepted or will a hard copy need to be available?

A: Provided in webinar

Q: Just to clarify I run the UK subsidiary of an Italian component manufacturer, will the products imported need to be UKCA marked (either by the manufacturer in Italy or by us in the UK) to be sold into the UK market?

A: Provided in webinar

Q: Will Importers to UK be required to add UKCA mark or will we still be accepting CE marking?

A: Provided in webinar



Q: I purchase products from the EU and then sell in the UK, NI and EU. Will I need to certify the products, or will my supplier need to do this?

A: Provided in webinar

Q: Please clarify entered the market, does this mean each individual purchase order or when the product type first became available for sale?

A: Provided in webinar

Q: For long lead equipment ordered and specified under the CE rules, but not now due for delivery until 2022, is the CE marking alone acceptable as it is after 1st Jan 2022? Or does the manufacturer/end user require to re-certify under the new UKCA mark?

A: Provided in webinar

Q: With no MRA in place between UK and EU, can ISO17025 be used to encourage sharing of data between UK and EU (and vice versa) in order to re-issue test reports in both areas?

A: Provided in webinar

Q: If after Jan 22 you import second-hand equipment to GB, does the equipment need to comply to current regs/stds in the UK. Similar concept to importing into EAA at the moment.

A: Provided in webinar

Q: How does the end user determine when goods have been placed if supplied after 01/01/2022?

A: Provided in webinar

Q: Under PUWER 1998, there is requirement the CE documentation? Will this change?

A: Provided in webinar

Q: Has the marking been agreed for sheet metal duct-work?

A: Provided in webinar

Q: We are a German company with a UK company also, We have suppliers who manufacture parts for our systems that are installed in customer sites. We normally collate



all of the CE marked equipment, install this and then CE mark the entire completed system. How do we get our EU partners to become UKCA marked or is that not needed?

A: Provided in webinar

Q: After Jan 22, can we use CE only marked items in an assembly if we risk assess them and decide they are safe to use, eg. because they meet the same Essential Safety requirements?

A: Provided in webinar