

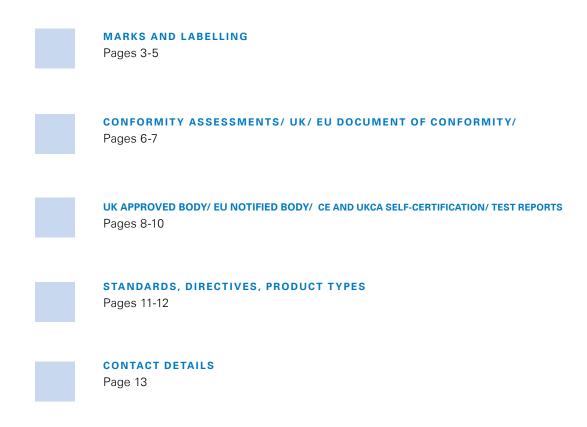
FAQ - IMPACT OF BREXIT

UKCA and UK(NI) Marks
What to do, How to do it, When to do it!

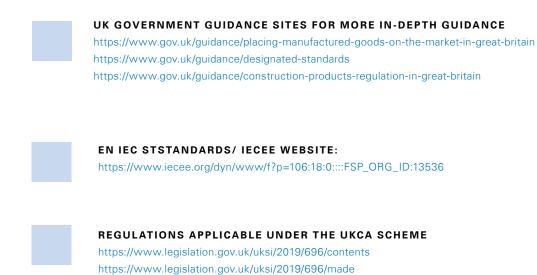
Our Online Seminars held on 17th/18th November, 2020



Shared knowledge about



And more goverment guidance on...



Marks and Labelling



UKCA Mark (United Kingdom Confiormity Assessment)

UK(NI) Mark (for Northern Ireland only)

Do I need a UK adress on the product, if I import from the EU?

 Yes, the importer address should also be placed on the product. The legislation specific to your product may make allowances for the importer details to be placed elsewhere if it is not practical to place them on the product.

SIMILAR QUESTIONS

- Is there any requirement for parity of appearance of CE and UKCA mark? I.e. if CE is on packaging and on product, will UKCA mark only on product be sufficient or should it be equally visible as CE mark?
- Does the UKCA mark apply to only the product marking or does it also apply to product packaging - or within instructions?
- UKCA on the product? So we have to emboss our product and not just have on packaging (Toy supplier)?
- By UKCA on product does this mean the actual product or on packaging is okay?

MULTI-QUESTION RESPONSE

Currently the UKCA scheme very closely resembles the CE scheme, so in almost all cases whereever you are required to affix a CE mark for the EU market you will be required to affix a UKCA mark for the UK market.

This is mostly on the product and often on the packaging also (in a few instances accompanying documentation is also accepted).

This will be defined in the legislation applicable to your product.

Is there a conflict to have both EU and the UK importer details on the product?

 No guidance has been given, however as long as each is clearly marked as such, so confusion does not arise.

How should I go on with the situation that I have less space on sunglasses and some other small products? Would it be ok to use the EU CE mark on the product and the UK CE mark on the packaging?

 Marking allowances will be defined in the legislation applicable to the product

Can products be dual marked with UKCA and CE marks?

 Yes, the CE mark is used to show conformity with the EU requirements whilst the UKCA mark is used to show conformity with UK requirements (excl. Northern Ireland)

CEN/CENELEC standards have the prefix BS EN..."

 The CEN/CENELEC standards begin 'EN'. These are European standards, The 'BS' designates the standard as a British standard. So a 'BS EN' is suitable for both the UK and the EU.

Is it possible reduce the dimension of the MARK?

 The standard minimum dimension is 5mm in height, however legislation applicable to your product may allow for a smaller dimension or for the mark to be placed on packaging or accompanying documentation.

Marks and Labelling

Does the UKCA mark have to be black or white or can it be a different colour/embossed?

No advice has been published regarding the colour to date, however there is advice stating 'You must ensure that the UKCA marking is easily visible, legible and permanently attached'. Given this advice it is likely an embossed mark of a different colour would be acceptable as long as it was easily visible and legible.

Is there a chance that UKCA (or a substantial part of UKCA) could be scrapped in a Brexit deal scenario?

 The UKCA scheme is set to proceed in the event of either a 'deal' or 'no deal' Brexit scenario. That said if a deal is reached then there could potentially be changes, although no major changes are expected.

Do we need the adress of an UK importer on all products, e.g. textiles which are not CE products like PSA sunglasses?

 The exact requirements for importer details are given in the legislation specific to the products. Applicable legislation should be reviewed.

At which pack layer should the marks go on as of 1/1/22 -1/1/23 and as of 1/1/23? e.g. on the device, the pack, the manuals, to a combination? - Good question, guess same as CE right now: on the rating label, DoC in manual and sales carton?

 The UK marking location currently aligns with the CE marking location. This is normally on the product but additional allowances/ requirements may be listed within the applicable product legislation

Does the umbrella legislation call out the UKCA mark?

 Yes, The Product Safety and Metrology etc. (Amendment (EU Exit) Regulations 2019 calls out the UKCA mark in Annex 2, it is referred to elsewhere in the regulation as the UK marking.

With regards to rating plates on power tools do they have to be in English?

 Yes, as English is the official language of the UK, rating plates should be in the English Language.

Heard that cosmetic items are going to need UKCA as well. Any detailed requirement?

Cosmetics were added to the UKCA products requiring special rules on the 10th November 2020. The UK Government have advised 'Further guidance will be published shortly'

SIMILAR QUESTIONS

- You mentioned that CE mark is fine from NI to GB, is this time limited? Or indefinite? Also will this still apply once national legislation diverges from EU directives?
- About NI: So any UK company (with NI presence) can continue to place CE marked products on the UK market, whereas other companies will need the UKCA marking?

MULTI-QUESTION RESPONSE

It is only Northern Irish Businesses (with headquarters registered in NI or GB) that can take advantage of the unfettered access and supply CE marked products to Great Britain. This will continue regardless of any divergance between EU and UK legislation until at least 2025 when the Northern Irish Elected Institutions may vote on it.

Note: The EU (Withdrawal Agreement) Act 2020 includes provision for the Government to define a qualifying status for goods and businesses in Northern Ireland benefitting from unfettered access.

If a product is shipped to UK (GB+NI) + EEA/EU, it is illegal for a product to have the UKNI mark in the EU?

 Correct, if the UK(NI) mark is present on a product it cannot be supplied to the EU single market (it means the CE mark is only valid for Northern Ireland). If you wish to place products on the market in all three locations (Great Britain, Northern Ireland, and the EU) you require CE without UK(NI) mark and UKCA mark (CE for EU and Northern Ireland, and UKCA for Great Britain).

Do we need importer information with CE mark for NI when product is manufactured in EU?

 No, as Northern Ireland will continue to use the CE scheme there are no additional requirements.

The CE marking should be the only marking of conformity indicating that a product is in conformity with Community harmonisation legislation" according to 765/2008/EC Regulation. Is it allowed to have both marks (CE and UKCA) on the products?

 Yes, UKCA shows compliance to UK legislation and CE shows compliance with EU legislation.

Marks and Labelling

SIMILAR QUESTIONS

- Can we place both UKCA & CE on our products?
- Is it allowed to show on nameplates and in the documentation both in parallel (CE and UKCA) when selling in complete Europe + UK a certain (same) product, correct?
- If you have a product that is sold to a UK company who also have stores in Eire is CE marking and UKCA dual marking acceptable?

MULTI-QUESTION RESPONSE

Yes, the marks each relate to different markets (EU and UK)

Are audits required by UKCA before labeling the marking on the product?

• No, like the CE scheme UKCA is a self declaration.

Will any kind of additional testing by third parties or the addition of "British deviations"/standards in existing CB reports be required before the UKCA is labeled? And where do you find which EN IEC standards correspond to which British?

 UK national differences/ deviations continue to be the available on the IECEE website: https://www.iecee.org/ dyn/www/f?p=106:18:0::::FSP_ORG_ID:13536

Do we need to mention a UK address on our products when our UK customer distributes our product from the UK back on the EU market?

• The product should be marked with the manufacturers' address. If you are shipping products into the EU and the manufacturer address is in the EU then no additional address is required. If you are shipping to the EU and the manufacturer address is not in the EU then the importer address in the EU is required in most cases.



SIMILAR QUESTIONS

- Slide 27: If you wish to sell PPE's in UK after 1st January 2022, you will need to add a UKCA mark? And as the product is a PPE, you will need to have a UK Notified Body to either test the product or approve the testing already done, before you can add a UKCA mark to the product?
- Can a UKCA mark be added in 2021 without a UK Notified Body approval, or is such UK Botified Body approval required before adding the UKCA mark?

MULTI-QUESTION RESPONSE

In order to add a UKCA mark products must first have certification from a UK Approved Body where the relevant legislation requires it. The product can continue to be sold in the UK with just CE mark until 1st January 2022.

What about product already displayed in shop-floor at retailer? Should the importer supply UK Energy Labels on 1st January 2021 and then the New Energy label on 1st March 2021?

• If you have already placed your good on the UK market (or in an EU country) before 1st January 2021, you do not need to do anything new. These individual goods can continue to circulate on either market until they reach their end user and do not need to comply with the changes that take effect from 1st January 2021.

When we refer to the cut off dates of "1/1/22" or "1/1/23", at which supply chain stage this applies e.g. products manufactured as of these dates? products shipping to customers? etc.

The cut off dates are in reference to placing the products in the market. Please refer to the below link about the defintion on the "placing on the market" https://www.gov.uk/guidance/placing-manufactured-goods-on-the-market-in-great-britain

Conformity Assessments UK/ EU Document of Conformity/



If both UK and EU based body conformity assessments are in place, whether a product could carry UKCA & CE mark if marketed only in UK (GB&NI) from 2022?

 If you are selling your product in both Great Britain and Northern Ireland then you will need to dual mark your product with UKCA (for Great Britain) and CE (for Northern Ireland).

Can a distributor who imports my product be my manufacturer's UK representative listed in the UK DOC?

• If the applicable legislation requires an authorised/responsible person in the UK then your distributor can take on this role assuming they meet the requirements in the legislation applicable to your product. In this case you will need a contract with your distributor for this role.

For the CE mark in 2021, can the EU representative listed in the DOC live in UK or must reside in the other 27 states? Currently our EU rep lives in UK.

 An EU representative must be located in the EU, UK based representatives will no longer be recognised as an EU representative after 31st December 2020.

Is it sufficient to use a phone number for the UK importer contact?

 In almost all cases where importer details are required the goods must be labelled with the importer name/trademark and contact address. Details of requirements can be found in the legislation applicable to your product.

Is it correct on the DoC the references to UK regulations before they were amended to introduce UKCA assessment and marking?

• The regulations applicable under the UKCA scheme (without special rules) are ammended by 'The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019' https://www.legislation.gov.uk/ uksi/2019/696/contents, which introduces the UKCA marking.

SIMILAR QUESTIONS

- Since BS EN standards are the adoption of EN standards is it possible to reference EN standards in the UK DoC?
- If products are tested after EN standards why should we then list BS-EN standards in the UK DoC?

MULTI-QUESTION RESPONSE

The BS prefix will no longer be required, the UK has now published a list of Designated standards that may be referenced: https://www.gov.uk/guidance/designated-standards

Can I issue UK DoC based on EU DoC, given the standards are same? Is there any local testing required or devices can be tested in any member state country? Any legal issues to take care of?

Yes, you can issue a UK DoC based on an EU DoC and Technical file if the involvement of a Notified Body was not required. If a Notified Body was required for the CE then you will require certification from a UK Approved Body before a UK DoC can be issued.

Conformity Assessments UK/ EU Document of Conformity/

Do we always need to deliver the DoC along with the product (manual) or can it be provided on demand (are there the same rules depending on the certain regulations as in EU according this item)?

• The UKCA scheme is very similar to the CE scheme and in almost all cases where you are required to provide a copy of the DoC with the product for CE requirements in the EU you will be required to provide a copy of the UK DoC for the UK. The legislation applicable to your product will contain the relevant requirements.

Where conformity assessment is provided by EU lab, can a UKCA mark be applied?

 Where third party conformity assessment is required by the applicable legislation, conformity assessments carried out in any location may be acceptable providing that the laboratory holds suitable accreditation, the correct standards were used, and the test report is then certified by a UK Approved Body.

By "accompanying documentation" does this include instruction manuals / packaging?

Accompanying Documentation is any document accompanying the product to the end user (normally within the product packaging) i.e. User Manual, Safety Information etc. Packaging is usually refered to seperately, details can be found in the legislation applicable to the product.

SIMILAR QUESTIONS

- Is a separate DoC is mandatory? Can one DoC which include EU and UK required information apply to both UK and EU
- Why can the EU and UK DoC not be merged into one?

MULTI-QUESTION RESPONSE

No guidance has been published to address this. However, a Declaration of Conformity is a legal document. One is a declaration under EU law and the other a declaration under UK law - with their contents clearly defined in their respective legislation. As such we do not recommend combining them.

Is it necessary to reference the amending SI 2019/696 in DoC along with the existing SIs for EMC, radio, etc? (bearing in mind the existing SI's are directly relating to EU legislation, not UK)

The BEIS (UK Department for Business, Energy & Industrial Strategy) have not yet released any advice on this subject. However, when contacted they advised information would be forthcoming.

EU Document of Conformity/

As a UK manufacturer can our EU DoC continue to use a UK name and address?

Yes, the Declaration of Conformity address should be that
of the manufacturer (or the address of the Authorised
Representative - where allowed by the specific product
legislation).

UK Approved Body/ EU Notified Body / Scope of TÜV Rheinland UK

Will TUV Rheinland UK Ltd. get UK Approved Body for Radio Equipment legislation?
Will TUV Rheinland be an Approved Body for all the areas where you are currently a Notified Body?
Which exemptions?

Our initial application which is expected to be achieved by June 2021 will cover the below scope, however we are planning to extend the scope shortly after accreditation is granted to include all areas within the UKCA marking scope that we currently cover from our EU Notified Bodies.

N°	CODE/SCHEME (if applicable)	Scope Description
1	Supply of Machinery (Safety) Regulations 2008 (EU-2006/42/EC Machinery Directive)	Module B/ Annex IX: All product categories in annex IX exc. 12.1./12.2.
2	Pressure Equipment (Safety) Regulations 2016 (EU 2014/68/EU Pressure Equipment	Module B, Module D, Module F, Module G - Annex III
3	Radio Equipment Regulations 2017 (EU-2014/53/EU Radio Equipment Directive)	Module B/ Annex III
4	Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres Regulations 2016 (EU - 2014/34/EU Equipment and protective systems intended for use in potentially explosive atmospheres (recast))	Module B / Annex III
5	Personal Protective Equipment Regulations (Regulation (EU) 2016/425 as brought into UK law and amended)	Module B / Annex V, Module C2 / Annex VII, Module D / Annex VIII: as applicable to the following product groups:
	(EU - 2016/425 Personal protective equipment)	Equipment providing buoyancy aid, Equipment providing eye protection, Equipment providing face protection, Equipment providing foot, leg and anti-slip protection, Equipment providing general body protection (clothing), Equipment providing hand and arm protection, Equipment providing head protection, Equipment providing protection against cold [> -50°C], Equipment providing protection against cold [cold >-50°C], [extreme cold <-50°C], Equipment providing protection against heat [< 100 °C], Equipment providing protection against heat [> 100°C and fire and flame], Equipment providing protection against heat [Heat<100°C], [Heat>100°C and fire], Protective Equipment against drowning, Protective Equipment against mechanical risks, Protective Equipment against substances and mixtures which are hazardous to health, Specialized areas of competence: Firemen suits, Specialized areas of competence: High visibility clothing, Specialized areas of competence: Protective equipment for diving
6	Toys (Safety) Regulations 2011 (EU - 2009/48/EC Safety of toys)	Module B / Article 20: all products in Article 2
7	Electromagnetic Compatibility Regulations 2016 (EU-2014/30/EU Electromagnetic compatibility	Module B: Annex III, Part A

UK Approved Body/ EU Notified Body



As a UK manufacturer, we are migrating products to an EU based Notified Body to continue CE marking. Do you forsee any issues following Brexit for any devices still bearing a CE mark number from a UK based Notified Body? How could we mitigate any risk to import?

If products requiring a Notified Body were placed on the EU market prior to 1st January 2021 they will remain acceptable, after the 1st January 2021 if placing the products on the EU market then an EU Notified Body must be used (and corresponding Notified Body number).

What will happen to the test reports issued by UK test houses after 1st January 2021? Is there any MRA in discussion between UK and EC? Does this mean the power supply manufactueres have to have UKCA?

• Test reports remain unaffected for the purpose of UKCA and CE self declaration. Power supplies (excluding those considered component parts for building in) will require CE mark for the EU and UKCA mark for the UK (however both Declarations of Conformity can be based on the same testing evidence).

How will we know if our products need a notified body?

 This information can be found in the specific UK legislation/ EU Directive applicable to your product. As UK and EU currently align in almost all cases where an EU Notified Body is required for the EU a UK Approved Body will be required for the UK.

If I am a manufacturer located in France will I be able to apply to a UK Approved Body for the CE + UK(NI) for Northern Ireland?

 If your product requires the use of a UK Approved Body / EU Notified Body you will need to apply for certification from each. That said some companies will maintain both a UK Approved Body and an EU Notified Body (such as TUV Rheinland intends to do) allowing them to issue certification for both UK and EU.

Is there a possibility that "Approved Bodies" will not be authorised in time for all the relevant regulation areas (for UKCA conformity assessment)? Are there other Approved Bodies in the UK, or will be?

• Any EU Notified Bodies located within the UK will automatically become UK Approved Bodies on 1st January 2021 so we can be confident that the vast majority of the total scope will be covered by a UK Approved Body. That said there is a risk that for a few products no UK Approved Body will have them on their scope before the end of the transition period, in which case the relevant authority should be contacted for advice.

SIMILAR QUESTIONS

- What about Chinese testing houses, are they UK Approved or EU Approved Bodies, is there a list of Approved Bodies?
- Will there be a UK database of UK Approved Bodies like the EU "NANDO" database?
- Can a EU Notified Body based in EU become a UK Approved Body?
- Is TÜV Rheinland in EU except UK planning to get scopes for UKCA NB?

MULTI-QUESTION RESPONSE:

• UK Approved Bodies must be located in the UK, just as EU Notified Bodies must be located in the EU. These bodies may make use of or accept test reports from test houses in other countries. Whilst it has not yet been published there is a plan to publish a UK Approved Body list (likely on the Government UK website).

How long would it take you to review an EU NoBo certificate and report for a safety component before issuing a UKCA Certificate? How could we mitigate any risk to import?

 The turn around time may vary depending on volume of requests (to be advised at time of quoting), however the process itself can be completed within a week if there are no complications.

UK Approved Body/ EU Notified Body

SIMILAR QUESTIONS

- What happened to the EU Type Examination certificate after 1st January 2021 issued by UK NoBo?
- What does UK based EU NoBo automatic transfer to UK assesment body actual mean? Is EU NoBo still be available in UK?
- Will EU type examination certificates issued by UK-Based NoBo remain valid for import to EU? Or become invalid on 1st January 2021?
- What about assesments that have been carried out by a EU NoBo and their acceptance within the UK. This is also a question to the extend of other certifications, eg, EU type approvals for functional safety.

MULTI-QUESTION RESPONSE:

As EU notified bodies located in the UK will no longer be recognised by the EU from 01.01.21 you will not be able to CE mark products based on a UK notified body certificate from this date (unless you transfer your certification to an EU based notified body before 01.01.2021). UK based notified bodies will automatically become UK Approved Bodies from 01.01.21, as such you will be able to use your Type examination certificate from the UK Approved Body for the purpose of UKCA marking.

CE and UKCA are self-certification

I was under the impression that CE and UKCA are self-certification. Has this changed? What would be the reason to ask a notified body to look over anything apart from peace of mind? If the testing performed meets standards used in that market don't you just fill out a Declaration and save the results like we used to? (and register the product).

For many Directives/Legislation no Notified Body/Approved Body involvement is required, however some Directives/Legislation do require the involvement of a Notified Body. The UKCA requirements very closely mirror the CE requirements, so if you do not require the involvement of a Notified Body for your CE you will not need a UK Approved Body for UKCA. If you are unsure if you require the

 involvement of a Notified Body/Approved Body you can review the applicable Directives/Legislation or alternately contact us and we will be happy to assist.

For CE marking for EU directives that allowed self-certification - will UK companies still be able to self- certify for EU export - i.e. affix a CE mark or will they have to use a notified body in the EU?

 If the relevant directive does not require the involvement of a Notified Body you may continue to CE mark as normal

Test Reports/ Certificates

Are test reports issued within EU, accepted by UK to certify products in line with UKCA?

 Where third party conformity assessment is required by the applicable legislation, test reports issued outside of the UK may be accepted by a UK Approved Body at their discretion for certification. This is only possible if the testing laboratory holds suitable accreditation and the correct test standards were applied.

Is it certain, that TUV Rheinland UK Ltd. will be able/ allowed to issue UK Certificates purely based on document review with out re-testing?

- Test reports would undergo an in depth review by a certifier, depending on their findings their could potentially be
 4 outcomes. (reports must be to UK standards or standards harmonized with them and be from an ILAC accredited laboratory and within their scope of accreditation)
- 1. Results are consistent and appear correct etc: Accepted and Certification issued
- 2. Minor errors etc: Request for report correction before certification can continue
- 3. Ambiguous results etc: Partial testing may be required to confirm results
- 4. Major errors, inconsistant results etc: Certification Rejected

Standards, Directives, Product Types



The EU harmonised standards year versions that gives/cease to give presumption of conformity can be found in the respective EU directive harmonised standards list. What about the BS year versions that give presumption of conformity, where can we find the similar harmonised standards list as per EU directive?

 The UK Government is publishing a full list of acceptable standards. These have been called 'Designated Standards', details can be found here: https://www.gov.uk/ guidance/designated-standards

Is there a gap analysis between the EU and UK regulations?

• There is no gap analysis as such but the linked document below shows many of the changes that were made to the directives to make them UK legislation as a result of Brexit: https://www.legislation.gov.uk/uksi/2019/696/made

SIMILAR QUESTIONS

- When UK designated standard will be released?
- Does UK have a list of standards as provided in the Official Journal of the EU that can be used to provide a presumption of conformity?

MULTI-QUESTION RESPONSE:

 UK Designated Standards can be found here: https://www.gov.uk/guidance/designated-standards

For standard products, not UKCA marked, there will be modification on requirements?

Example: a waste bin for kitchen

 In most cases the changes are non-technical, you can see most of these changes here: https://www.legislation. gov.uk/uksi/2019/696/made

For the NB (notified body) products (gas, ppe etc.) when having an EU NB with CE mark, will this be accepted by the UK after 1st January 2022?
EU -> UK without UKCA and UK representation?

 No, from 1st January 2022 you will be required to use UKCA and gain certification from a UK Approved Body.

Are there any concerns (probably from EU community) that adding CE + UKNI effectively means that the product is not meeting CE requirements?

Products marked with UKNI will not be be allowed to enter the EU single market.

For the UK legislation to be noted on the UK DoC, will these have Statutory Instrument reference numbers?

 The Statutory Instrument numbers are not required on the UK DoC

Standards, Directives, Product Types



Where can we find special rules of Construction Products?

 Guidance for construction products can be found here: https://www.gov.uk/guidance/construction-products-regulation-in-great-britain

What would happen if the UK do not have Approved bodies for all areas (like for specific Construction Products

 The BEIS (UK Government Department for Business, Energy & Industrial Strategy) is monitoring Approved Body coverage and is in some areas allowing the use of EU Notified Bodies.

Why "should" EU and UK DoC be separate documents, is there a legal requirement prohibiting a combined EU + UK DoC (provided that particular requirements of EU + UK are fulfilled)?

 The UK DoC is a UK legal document and the EU DoC is an EU legal document. As such it is advisable to generate separate documents.

Is a legal representative within the UK needed for manufacturers/suppliers from outside the UK?

 In legislation for most products the importers must take on responsibility for products they import, however some product legislation allows or mandates a local representative. It is suggested to review the legislation applicable to your product.

Contact us!



Whereever you are in your transition, we are there to help if help is needed.

TÜV Rheinland UK supports you in the following ways:

- Information
- GAP Analyses
- Readiness Reviews
- As an EU Notified Body
- As a UK Approved Body

You can contact our experts at any time.

Just reach out to us directly oror your closest international TÜV Rheinland office.

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