Frequently Asked Questions- 'Brexit' and Product Certification

Please note:

-The following questions and answers assume that the UK will leave the EU **without** a deal. If a deal is reached or a delay agreed, we will update these FAQs based on the terms of that deal.

- Through this FAQ, we use the term 'transfer', in legal terms we will novate the contract from our UK notified body and the Netherlands notified body.

- All questions should be directed to Brexit-ProductCertification@bsigroup.com and all media enquiries should be sent to pressoffice@bsigroup.com

Transfer of Notified Bodies

Q: What is a notified body?
A: A notified body (NB) conducts conformity assessment activities under the relevant EU directives. This usually involves an audit of the manufacturer's quality system and may include initial and ongoing testing of their products (depending on the classification of the device). Once all the relevant assessment criteria have been determined by the notified body, it issues a EC certificate to the manufacturer to support their affixing of the CE marking. A notified body **does not** give permission to affix the CE marking.

Q: Why am I being transferred to the Netherlands notified body?
A: As a client focused business, BSI has taken the decision to establish a notified body in the Netherlands. This will ensure that in as many cases as possible, BSI will be able to deliver EU market access for our clients in advance of the UK's withdrawal from the EU. It is worth noting, however, that you will have the option not to transfer to the Netherlands NB, although staying with the UK approved body will only provide the UKCA mark.

Q: Are all EC certificates being transferred over to the Netherlands notified body?
A: BSI has to apply for designation for individual directives, it is not a case of transferring them all over. We will be contacting you in regard to the status of your individual directive.

Q: Will I have the same EC certificate number when my certificate is transferred from the UK notified body to the Netherlands notified body?
A: All certificates that contain the UK notified body number (0086) will be changed over to the Netherlands notified body number (2797). However, if your certificate doesn't contain the notified body number, the certificate number will remain as is.

Q: Will you be charging me a fee to transfer my existing EC certificates?
A: No. All existing EC certificates within the scope of our notification will be transferred **free of charge.**

Q: How long will the transition period be?
A: If there is no deal, there will be no transition period. If a deal is achieved, the transition period will depend upon the deal agreed between the UK Government and the EU, particularly on access to the EU-27 markets and the acceptance of the CE marking for the UK market access.

Q: Why have some of my CPR certificates been novated over to the Netherlands NB, but not all of them?
A: Although BSI is a notified body in the UK and Netherlands there is a difference within the range of standards covered by each body. BSI Netherlands is progressing a further application to increase the scope within the Netherlands. It seems unlikely the notification process will be complete before Mid-April 2019.

If the UK leaves the EU without a deal, your current UK CE marking certification (0086) will still be applicable for you to use the UKCA mark for the UK market alone. Once we gain notification for your products we will contact you again and take you through a straight forward process to enable you to achieve CE certification with BSI Netherlands. In the event of a delay or deal, your UK CE marking certificate will remain valid for affixing CE Marking giving market access to the EEA which includes the EU and the UK.

The new UKCA, CE marking and the Kitemark

What is a UKCA symbol?
A: The UKCA symbol will replace the CE safety mark in the UK in the event of a no-deal Brexit. The new logo drawn up by the UK government stands for UK Conformity Assessed (UKCA). If the new logo is to be used, companies would have to change their packaging, advertising and element of the products themselves. The UKCA mark is not acceptable in the EU – it is only applicable to the UK market.

Q: Will BSI be charging for UKCA in a 'no-deal' scenario?
A: All clients will be given an opportunity to transfer to the Netherlands notified body or to remain with the UK approved body. There will be no charge for transferring to the Netherlands and the associated EC certificate, nor will we charge for the UKCA certificate if the clients wish to remain with the UK approved body.

If you require both certificates, an additional contract will be required, for which you will be charged. Visits will be combined and where necessary type and audit testing.

Q: Will Kitemark be accepted in European markets after 29 March?
A: Yes. Kitemark is **not affected by Brexit.** It is a voluntary mark offered by our global business and assists markets around the world.

Products already on the market

Q: What about my products which are already on the market – and how the new number will affect these?
A: The concept of placing on the market refers to each individual product, not to a type of products, whether it was manufactured as an individual unit or in series. It relates to the first making available on the Union (EU-27) market, i.e. the first supply of a good for distribution, consumption or use after the manufacturing stage.

Placing on the market does not require physical delivery of the product but does require that the manufacturing stage has been completed. If the product has been placed on the market before the date issue date on the new 2797 certificate then the previous UK issued certificate should be used. If the product is placed on the market after the issue date on the 2797 certificate then the new 2797 certificate should be used.

Here are some scenarios in which you might find yourself:

1. **Goods physically in the distribution chain or already in use in the EU-27 market on the withdrawal date.**

Example: a cosmetic product held in the EU-27 by a wholesaler with a view to onward distribution or already on the shelf of a department store; an X-ray machine (medical device) certified by a UK Notified Body held in the EU-27 by a wholesaler or already supplied to a hospital in the EU-27, where it is in use.

These goods are considered as placed on the Union (EU-27) market before the withdrawal date and can therefore continue to be made available in the EU-27 market or remain in use with no need for re-certification, re-labelling or product modifications. This is without prejudice to the obligation to appoint a new 'responsible person' established in the EU-27 where the current one is UK-based.

2. **Goods manufactured either in the EU or in a third country, sold to an EU-27 customer before the withdrawal date after the manufacturing stage was completed but not yet physically delivered to the EU-27 customer on that date.**

Example: an X-ray machine manufactured in the US and certified by a UK Notified Body has been sold to a Dutch hospital on 10 days before the withdrawal date (=date of placing on the market, i.e. date of the transaction) but will arrive at Dutch customs on 5 days after the withdrawal date.

Same as the goods under Q&A No. 1. The date of placing on the Union (EU-27) market is the date of the transaction between the manufacturer and the EU-27 customer after the manufacturing stage was completed. Placing on the market does not require physical delivery of the product.

3. **Goods imported into the UK from a third country or manufactured in the UK, subsequently sold to an EU-27 customer before the withdrawal date but physically delivered to the EU-27 customer as of that date.**

Example A: an X-ray machine manufactured in the US and certified by a UK Notified Body is sold to a UK wholesaler on 1 month before the withdrawal date and imported by the latter into the UK on 3 weeks before the withdrawal date. The UK wholesaler then sells it to a Dutch hospital 1 week before the withdrawal date and the X-ray machine arrives at Dutch customs 1 week after the withdrawal date.

Example B: an X-ray machine manufactured in the UK and certified by a UK Notified Body is sold either directly to the Dutch hospital or via a UK distributor, in both cases the date of the transaction with the Dutch hospital is 1 week before the withdrawal date, arrival at Dutch Customs is 1 week after the withdrawal date.

In both examples, same as the goods under Q&A No. 1 and 2. The date of placing on the Union (EU-27) market is the date of the transaction between the UK economic operator (manufacturer, importer or distributor) to the EU-27 customer. Placing on the market does not require physical delivery of the product.

4. **Goods imported into the UK from a third country or manufactured in the UK before the withdrawal date, subsequently sold to an EU-27 customer as of the withdrawal date.**

Example A: a circular saw (machinery) manufactured in the US and certified by a UK Notified Body is sold to a UK wholesaler on 6 weeks before the withdrawal date and imported by the latter into the UK 2 weeks before the withdrawal date. The UK wholesaler then sells it to a Dutch factory 1 week after the withdrawal date and the circular saw arrives at Dutch customs 2 weeks after the withdrawal date.

Example B: a circular saw manufactured in the UK and certified by a UK NB is sold either directly to the Dutch factory or via a UK wholesaler, in both cases the date of the transaction with the Dutch factory is 1 week after the withdrawal date, arrival at Dutch Customs on 2 weeks after the withdrawal date.

In both examples, the goods are placed on the Union (EU-27) market after the withdrawal date as the date of their first making available to an EU-27 customer is on or after the withdrawal date. The goods are considered as imports from a third country and will have to fully comply with the provisions of Union law applicable at the time of their placing on the market. This means in particular that the goods will have to have been certified by an EU-27 Notified Body, where a third-party intervention in their conformity assessment is required. Where applicable, they will also have to indicate the details of the EU-27 importer and of an EU-27 'responsible person'.

Other questions

Q: What are the different transitions options available for me?
A: For clients which fall under the Netherlands notified body scope, there are two options available:

1. You accept the transition to the Netherland NB (no action is required). This will result in an EC certificate that supports your CE marking and will allow you to sell into the EU-27, EEA and the UK markets (UK for a limited period)
2. You opt out and stay with the UK approved body. You will receive a UKCA certificate to support your UKCA marking.

Q: Will I need to have my products re-tested and does it need to be tested by an EU body?
A: If you transfer from our UK notified body, the Netherland notified body will accept the previous test work. There will be no need to re-test.

Q: How will this affect my relationship with the Republic of Ireland?
A: After Brexit, products sold by a UK manufacturer into the Republic of Ireland will need to meet the CE marking requirements using an EU-27 recognised notified body, such as BSI Netherland (2797)

The Republic of Ireland will remain part of the EU and will be one of the EU-27, therefore, to place a product on the market in the Republic of Ireland, it must be CE marked.

If an Irish manufacturer wishes to place products on the UK market, they require either valid CE marking supported by a recognised EU-27 notified body or the UKCA mark supported by a UK approved body.

Q: Where can I find further information on my responsibilities as a manufacturer?
A: Please see the UK Government's official advice by regulation:

BED: https://www.gov.uk/guidance/placing-energy-related-products-on-the-uk-market

CPR: https://www.gov.uk/guidance/construction-products-regulation-if-there-is-no-brexit-deal

GAR/Lifts/MED/MID/PED/PPE: https://www.gov.uk/government/publications/trading-goods-regulated-under-the-new-approach-if-theres-no-brexit-deal/trading-goods-regulated-under-the-new-approach-if-theres-no-brexit-deal

TPED: https://www.gov.uk/government/consultations/carriage-of-dangerous-goods-and-use-of-transportable-pressure-equipment-reference-changes