

Brexit Special

March 2019



With Brexit imminent, given the limited information available to us, we attempt to clarify and foresee the implications that this will have on manufacturers of equipment that currently requires the CE Mark. If there is no deal, then the changes detailed in this newsletter will apply after 29th March 2019, if the 'withdrawal agreement' is accepted then the current CE requirements will apply until the end of 2020 (unless alternative arrangements are agreed in due course), of course if Brexit does not happen at all (or the UK remains in the EEA), it is business as usual.

Application of Standards

Let us get the easy part out of the way at first. Last year the EU standards bodies CEN and CENELEC approved the UK's continuing membership, therefore the standards that apply will remain the same. 'EU harmonised standards' will become 'UK designated standards' but the technical content should not change; please note that some published standards have national deviations and this will continue. With the exception of some labelling the construction requirements for your equipment should remain unchanged. CEN and CENELEC are non-political organisations and the UK through BSI the National Standards Body will continue to participate in the Technical Committees in order to publish and revise standards.

It should be noted that compliance with harmonised standards is voluntary but they prove to be a valuable route for compliance with applicable regulations since this demonstrates *state of the art* compliance. UK and EU law that relates to products is written in general terms, however the standards that could be used to demonstrate presumption of conformity with applicable regulations go into detailed technical and documentation requirements.

Placing Equipment on the UK Market

If the equipment is covered by a CE Marking directive the UKCA Mark will apply. Since CE Marking Directives are at present implemented into UK law as secondary legislation in the form of regulations, (e.g., the Machinery Directive 2006/42/EC is implemented in UK law as The Supply of Machinery (Safety) Regulations 2008 Statutory Instrument No. 1597 2008), it would make sense to keep these regulations the same but the declaration of conformity should no longer refer to EU directives. At present there has been no confirmation as to whether the title or statutory

The UKCA Mark logo consists of the letters "UK" stacked above the letters "CA" in a bold, black, sans-serif font. The logo is set against a light gray grid background.

Instrument number of the regulations will stay the same or if they will be revised. We therefore advise refraining from changing your documentation until such information has been confirmed.

In addition manufacturers will need to apply the new UKCA mark to their equipment. Further information can be found at

<https://www.gov.uk/government/publications/prepare-to-use-the-ukca-mark-after-brexit>

Exporting Equipment into the European Economic Area (EEA)

If you export equipment into the European Economic Area (the remaining 27 members of the EU plus Iceland, Liechtenstein and Norway) the CE requirements will apply as before but there must be someone in the EEA who has to make the technical file available following an inspection request by an enforcement authority. If you have an office or agent in the EEA then this is the obvious choice; your importer or customer may retain the technical file, otherwise you will have to appoint an *Authorised Representative*. The declaration of conformity (or incorporation) will need to state the contact in the EEA and entry of your equipment into the EEA may be refused if representation in the EEA is missing from your declaration. Your technical file remains confidential as it may contain proprietary design information, we advise thorough vetting when appointing someone to hold the technical file for you in order to prevent your design from being copied.

If the equipment requires certification by a *Notified Body* (e.g. high risk machines specified in Annex IV of the Machinery Directive 2006/42/EC, medical devices and construction products) and it is currently certified by a UK Notified Body, the certification for the EEA will no longer be valid after 29th March 2019 and certification by a Notified Body established in the EEA will be required, although the UK will accept certification from a Notified Body in the EEA for a limited period of time that has yet to be specified. More information can be found at the following websites:

https://ec.europa.eu/growth/content/brexit---guidance-stakeholders-impact-field-industrial-products_en
<https://www.gov.uk/guidance/the-electronics-machinery-and-parts-sector-and-preparing-for-eu-exit>.

Unlike the present where goods are subject to free movement, it will be subject to inspection when crossing into the EEA and the equipment is likely to undergo checks at the border to verify that it has the appropriate certification. It is worthwhile checking that your documentation is correct, for example if you are sending a machine to France and the instructions are only in English, entry may be refused; likewise we advise having the equipment manual verified by a person who is proficient in the language of the country where the equipment is going to.



These additional checks could incur time delays and you should consider this in your delivery schedule. The border between Northern Ireland and the Republic of Ireland will become part of the outer land border of the EU, hence the EU will require such checks at this border.

Will the Kitemark Make a Comeback?

This is a question we have been asked recently. The answer is that the Kitemark (a trademark belonging to BSI) has never gone away as its symbolisation is different to the CE and proposed UKCA marks. Whilst the latter marks are mandatory to state compliance with regulations and can in many instances allow for self-certification, the Kitemark can only be applied after BSI has examined your product and quality system.

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