



Note concerning UKCA mark for PPE (version 2)

To : ESF members
Date : 18/11/2020

As we receive questions from members concerning the status of the UKCA marking on PPE, as will be required for products sold in the UK after the current transition period, BSIF, our UK member, has prepared, based on current the information they have from the UK authorities the following information. If you have any questions, please don't hesitate, we will try to answer as good as possible with the information available at this moment.

The UK Government has now published guidance on the use of the United Kingdom Conformity Assessment mark (UKCA mark). The link to the guidance is at the bottom of this page. The full "Guidance" package published was quite involved, from dealing with the status of Notified Bodies, who in the UK will be known as Approved Bodies, through to the application of the UKCA mark itself and also several pieces of guidance referring to the situation of trade in goods in and through Northern Ireland. Please be aware that these comments are made to the best of our ability and knowledge, and while they are believed to be correct at this time, details still remain subject to political negotiation and this interpretation should not be solely relied upon in your decision making.

The guidance published relates 17 items of "EU" originated legislation now adopted into "UK" legislation. These Regulations and Directives cover a large range of manufactured goods which will, for the purpose of placing on the UK market, move from the CE regime to the UKCA regime. PPE is one of the 17. Because of the wide range of goods, the guidance published is "high level" and general in nature and does not at this stage answer all the detailed questions necessary to effect a successful migration from the legislation Regulation (EU) 2016/425. The PPE regulations are arguably more complex than many of the regulations included in the guidance and further information on implementation has been requested.

Specific points of information from the guidance relating to the use of the UKCA mark and the UK domestic regime covering goods currently subject to CE marking

- The new UK domestic regime will come into force on January 1st 2021
- Current Notified Bodies in the UK will change in status to be "Approved Bodies". They alone will be empowered and responsible for product conformity approval decisions under the UKCA marking process
- You are encouraged to be ready to apply the UKCA mark and comply with its' requirements as soon as possible but...

- To allow business to adjust to the new requirements you will still be able to use the CE mark to place product on the UK market until the start of January 2022, in most cases. This is important as there has been a degree of misunderstanding / misinformation on this date. This based on valid certification (for cat II and cat III PPE) by a NB based in the EU27 (EU type examination certificates issued by a NB based in the UK become invalid as of the 1st of January 2021).
- The period from January 1st 2021 until December 31st 2021 can be seen as the “standstill period”. During this time you will still be able to use the CE mark where the requirements of the EU and UK standards remain the same.
- Further, until 1st of January 2023 for most UKCA goods manufacturers will have the option of affixing the UKCA marking on a label to the product or on an accompanying document. We are currently trying to ascertain whether this could mean over labelling on packaging.
- Goods can carry both the CE and UKCA marking as long as they are compliant with the requirements of both sets of legislation.
- As of and after January 1st 2023 the UKCA mark must in most cases be affixed directly to the product (same rules as in the EU PPE Regulation).
- From January 2021, EN standards that manufacturers currently work to, will become “UK Designated Standards”. There are no plans for the standards to change in this process, but similarly there is no mechanism for mirroring standards into the future.
- The situation for Northern Ireland is different. Avoiding a hard border between Northern Ireland and the Republic of Ireland, means that products compliant with the EU legislation (and thus CE marking) can continue to be placed on the market in Northern Ireland. The UKCA marking is not applicable in this part of the UK. Specific UKNI marking has been developed.
- Be aware that the status of economic operators might change. Distributors in the UK buying PPE from manufacturers in the EU will become importers, with the related obligations.

As said previously full details of the processes necessary for PPE are not yet available, but there are no plans to change technical requirements for products. We will do our best to update you on developments.

Link to guidance on using the UKCA mark from 1 January 2021:

<https://www.gov.uk/guidance/using-the-ukca-mark-from-1-january-2021>