businesscompanion
trading standards law explained

Other Applicable legal aspects to all Economic Operators

In this section

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Testing services

All economic operators within the PPE supply chain should be mindful when obtaining conformity assessment or carrying out document checks that they are not misled by certain certificates that are being provided as evidence of PPE conformity.

It is important to note that these certificates, often headed as ‘certificate of compliance’ or ‘certificate of conformity’ and carry the CE mark, are provided by companies offering certification and consultancy services. These services are not authorised by Member States and their services are not legal conformity assessments required by Regulations. They may also be produced by notified bodies that are sometimes not authorised for PPE.

Further detail can be accessed via the ESF Website where it lists some of the most known and frequently used certificate examples. https://www.eu-esf.org/covid-19/4513-covid-19-suspicious-certificates-for-ppe

What happens if I do not meet the legal obligations?

Due Diligence

A defence of ‘due diligence’ exists in consumer protection law. A person seeking to rely on this must prove that they took all reasonable precautions and exercised all due diligence to avoid an offence being committed.

The principles of this and the steps that may be taken, can be found in the Business Companion guide,

entitled Product safety: due diligence

https://www.businesscompanion.info/en/quick-guides/product-safety/product-safety-due-diligence#Duedilig enceprinciples

Corrective Actions

What are Corrective Actions and when are they required?

Corrective actions are required when either: -

- As an economic operator (i.e. a manufacturer, importer or distributor), you have reason to believe, or
- Another organisation in the supply chain or a Market Surveillance Authority notifies you,

that PPE you have placed or made available on the market is not in conformity with relevant legislation or poses a risk, Then you must take immediate appropriate corrective action necessary to remove the PPE and risk from the market.

It is an offence for an economic operator to fail to take the appropriate action required, or to provide information to or comply with, any of the requirements of the Market Surveillance Authority.

Corrections actions include but are not restricted to:

Withdrawal – which is 'any measure aimed at preventing a product in the supply chain from being made available on the market'

Recall - measures 'aimed at achieving the return of a product other than a safe product, that has already been supplied or made available to consumers'
Make sure that you have all the information you need to keep all businesses in the supply chain informed of any safety issues. This will help to meet your traceability obligations. Good practice would be (as a minimum) to follow the rule of 'one step forward and one step back' – in other words, that you hold details of the supplier who supplied you with the product or production materials and that you also hold details of those that you have supplied. This means product identification (batch/serial numbers, date of manufacture and supply, etc.)

PAS 7100:2018 on product recalls

BSI has published 'Code of Practice on consumer product safety related recalls and other corrective actions (PAS 7100:2018)'. This is publicly available and it helps businesses plan to deal with any potential safety issue that might arise with products they have placed on the market or distributed. The document can be obtained here: https://www.bsigroup.com/en-GB/pas7100-supporting-better-product-recalls/

Covid 19 related products and standards

During this period of COVID-19, recurring questions and issues have arisen as a result of the increased demand for PPE for COVID-19 purposes, particularly around applicable standards for face masks.

Face Masks

The relevant standards to look for are: -

PPE respirator face masks

- BS EN 149:2001+A1:2009 – European harmonised standard – this standard brings in the 3 categories of masks – FFP1, FFP2 and FFP3. FFP 2 & FFP 3 have been recommended by the WHO and NHS as appropriate PPE for protection against COVID-19.
- N95 & N99 – US standards equivalent to FFP2 & FFP3 respirator masks, respectively.
- KN95 – GB 2626-2006 – Chinese standards and type, style of mask name. Chinese standard GB2626:2006 is different to the EU EN149 standard in that KN95 masks are not tested to a technical standard by a third party (e.g.: notified body) whereas FFP2 and FFP3 masks are. KN95 is self-declaration by the manufacturer only. Masks quoting the KN95 standard should not be supplied as PPE in the UK

The majority of KN95 masks are consumer use pollution masks which are not designed for protection against category 3 hazards such as COVID-19. The HSE has stated that KN95 masks must not be used as PPE at work, unless authorised by the HSE, as their effectiveness cannot be assured. https://www.hse.gov.uk/safetybulletins/use-of-face-masks-designated-kn95.htm?utm_source=hse.gov.uk&utm_medium=refferal&utm_campaign=kn95-safety-alert&utm_content=home-page-new

See also the face shield example, with picture, included in the Manufacturer chapter of this guide.

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