

## Importers

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### What is an Importer?

Importers are not solely a re-seller of products but have a significant and vital role in ensuring only compliant PPE is imported and placed on the UK market. Importers have legal accountability for PPE compliance and product liability when PPE has been manufactured outside of the EU.

An Importer is defined in the regulations (Regulation (EU) 2016/425) as 'a person established within the Union who places PPE from a third country on the Union market.'

COVID-19 has meant that many import businesses, whether new start-ups or those that have adapted and increased their import base, now have the chance to assist in meeting the global demand for PPE.

### What are my legal obligations as an Importer? (during COVID-19 only)

If you are an importer, you will have a number of obligations that you need to meet to ensure the PPE you place on the market is in conformity with the regulations, prior to placing it on the market.

There are COVID-19 easements in place and the following takes these into account:

Importer obligations build upon those of manufacturers and the key is to ensure the manufacturer has fulfilled his/her obligations. It is therefore essential to read this Importer chapter alongside the Manufacturer chapter.

Importers must: -

- **Assure themselves that the PPE is compliant before it is placed on the market - gain assurance from the NB that the product is likely to pass and that the process for approval is in progress**
- For use by the Government/NHS - COVID-19 PPE does not have to undergo conformity assessment procedures but can be imported without the CE marking or Declaration of Conformity and purchased, provided it meets the EHSRs
- In relation to supplying the NHS, importers should have documentary proof that the manufacturer has met all their responsibilities. Remember that PPE for the NHS cannot be made available on the

general market

- PPE for the NHS market should be assessed and approved by the Market Surveillance Authority (HSE), under the easements
- For use in other sectors (non-NHS) – COVID-19 PPE can be imported and sold, providing conformity assessment procedures have begun, but not necessarily completed. These products will not be CE marked or have a completed Declaration of Conformity
- Importers supplying the non-NHS market should also have documentary proof from their manufacturers that they have met all their responsibilities
- Carry out sample testing and keep distributors informed of the results and actions taken regarding complaints or non-conforming PPE/recalls
- Include your name, trade name or trademark and postal address (unless already on the packaging)
- Ensure that the PPE is accompanied by instructions and safety information, in English
- Keep a copy of the (incomplete) Declaration of Conformity for 10 years (not applicable to NHS supply)
- Store and transport the goods so that they are not damaged which could jeopardise the EHSR of the PPE
- Immediately notify the UK enforcement authority\* of non-compliant PPE that you have placed on the market and immediately take corrective measures to bring it into conformity (or withdraw it or recall it, as appropriate). Where it presents a risk, inform the enforcement authority to that effect and give details as well as of any corrective measures taken. Respond to requests from the enforcement authority that might be necessary to demonstrate conformity and otherwise co-operate on any action required to eliminate risks which arise.
- Ensure that a chain of traceability exists, so that all those that have been supplied the PPE can be notified of any issues that arise

\*The UK enforcement authority is the Secretary of State who exercises these powers via the Office for Product Safety and Standards (OPSS, within the Department for Business, Energy and Industrial Strategy)

## **How do I meet my Importer Obligations?**

Know what you are importing, so that you can meet your responsibilities as an importer.

Check your products and their documentation

Examine the products (where possible) to ensure the legally required markings have been applied

In addition, ensure that the technical Standards being declared are correct, for example; PPE respirator face masks should follow the requirements of BS EN 149:2001+A1:2009 and face visors to BS EN 166:2002 and BS EN 168:2002.

Use the Technical Specification Guide which details the minimum requirements and applicable standards of PPE and medical devices for supply during COVID-19. This document has been provided for Government procurement for NHS only, however, it is a good starting point for knowing what standards and basic details are required.

<https://www.gov.uk/government/publications/technical-specifications-for-personal-protective-equipment-pp>  
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Finally, ensure the PPE is as expected, do the details on the product and packaging match up to the details on the documentation?

Ensure you have all the information you need to keep all those in the supply chain informed of any issues.

Continue to check subsequent consignments or batches as you receive them to ensure ongoing

compliance.

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