

Quality assurance of PPE and medical devices – Top lines and Q&A

- The term personal protective equipment (PPE) is used to describe an ensemble of products or medical devices that are used by frontline staff and patients to protect themselves or patients from possible infection from COVID-19.

Top lines:

- The PPE that you have received have been distributed by NHS Supply Chain, working in partnership with a number of organisations, including DHSC, NHS England and MOD.
- Before supplying a new product to the NHS, local resilience forums (LRFs) and other organisations, every product must meet the relevant technical and regulatory standards as set out by the Essential Technical Requirements for PPE and Medical Devices during COVID-19. This guidance has been written by the Health and Safety Executive (HSE) and the Medicines and Healthcare products Regulatory Agency (MHRA).
- Decisions on whether products are distributed are taken by a cross-Government regulatory panel including representatives from:
 - Department for Health and Social Care (DHSC)
 - Health and Safety Executive (HSE)
 - Medicines and Healthcare products Regulatory Agency (MHRA)
 - Office for Product Safety and Standards (OPSS)
 - The panel includes additional experts as required.
- The guidance on types of PPE is based on with World Health Organization (WHO) guidance for protecting health and social care workers from COVID-19. These standards and technical specifications can be found [here](#).
- The UK government has also published [clear infection prevention and control guidance](#) on appropriate PPE for health and social care workers. This has been written and reviewed by all 4 UK public health bodies and informed by NHS infection prevention control experts.
- All PPE procured from abroad that arrives at the Daventry warehouse is checked. If it is not CE marked then documents are sent to the UK regulators, HSE and MHRA, who agree to its release as the Market Surveillance Authorities for PPE and medical devices. Products are only released into the supply chain if the documents show the product is fit for its intended use.
- Sometimes this may require independent testing to ensure the PPE meets relevant standards of safety and performance.
- If you have concerns about a delivered products' suitability, please contact the PPE Customer Service Team via 0800 876 6802. This team will answer your query or escalate to HSE or MHRA as necessary.
- If there is a problem with a PPE product, report it via the online webform for [product complaints](#).

Process for quality assurance on new manufacturers

- Newly domestically manufactured PPE must conform to the same standards as all other PPE before we will buy it and it can be distributed to the NHS and social care sectors.
- Both the PPE Regulation and the Medical Devices Directive lay down essential requirements on health, safety and performance of the products they cover.

- However, both EU legal frameworks are technologically neutral and do not prescribe any specific mandatory technical solutions for the design of the products. Therefore, a number of technical solutions may be used by manufacturers to meet these essential requirements.
- Currently the requirement for conformity assessment and CE mark has been eased subject to HSE (for PPE) and MHRA (for medical devices) agreeing that products without a CE mark can enter supply for health care use only. They both have a robust process for assessing applications and data from manufacturers who want to supply or donate PPE to the UK. They will not agree to release PPE into the supply chain unless it meets essential health and safety requirements to ensure it is fit for the purpose intended, will work in line with stated performance and have been assessed as such.

Q&A:

1. Who has developed the essential technical requirements?

- The essential technical requirements for Personal Protective Equipment (PPE) and medical devices have been developed by HSE and HMRA on behalf of the NHS in the UK to ensure the rapid production of critical PPE for UK health and social care workers.

2. What do the essential technical requirements cover?

- We have focussed on priority areas of PPE and have introduced essential technical requirements for gowns (isolation and surgical), gloves, surgical masks, respirators, eye protection and coveralls for circumstances where either the manufacturer has not had sufficient time to fully comply with the regulations and obtain the CE mark or where an alternative use is proposed of an existing CE marked product.
- We will be taking a similar approach in due course to other items of PPE including aprons and are currently finalising our essential technical specifications in those areas with the UK regulators. A specification for aprons has been produced as a separate [document](#).

3. What benefits do the essential technical requirements provide?

- To enable UK manufacturing to proceed at pace, the Government has been working with HSE and MHRA to ensure essential technical requirements for COVID-19 products are in place and there is a clear process to secure regulatory approval for sale or supply of donated PPE produced against these requirements which does not involve the normal process of CE marking. There will still need to be agreement from HSE and MHRA before they can be used.

4. Why can the “normal” standards not just be applied more quickly?

- Current circumstances demand more rapid production, or alternative use of existing CE marked PPE or medical devices, without some of the administrative requirements normally required, but without adversely impacting on the safety of patients and health and social care workers.
- Where regulators find that PPE (as regulated by HSE) or medical devices (as regulated by MHRA) can ensure an adequate level of health and safety in accordance with the essential health and safety requirements laid down in Regulation (EU) 2016/425 or the requirements of Directive 93/42/EEC, they may authorise the making available of these products for supply to frontline health and social care for use in the COVID-19 response.
- The regulators may do this even though the conformity assessment procedures, including the affixing of CE marking, have not been fully finalised according to the harmonised rules, where the product is being sourced by Government and with the

caveat that they are not distributed outside of healthcare settings. MHRA call this exemption from medical devices regulation a 'derogation'. In relation to the PPE Regulation, this is known as a 'regulatory easement'.

5. Are the essential technical requirements 'weaker' than normal standards?

- Both the PPE Regulation and the Medical Devices Directive lay down essential requirements on health, safety and performance of the products they cover. However, both EU legal frameworks are technologically neutral and do not prescribe any specific mandatory technical solutions for the design of the products. Therefore, a number of technical solutions may be used by manufacturers to meet these essential requirements.
- The published essential technical requirements are based on WHO guidance and PPE produced under this approach will not present any additional risks to patient or health and social care professionals' safety or well-being.

6. What are CE mark and EN standards?

- A CE mark (short for *Conformité Européenne*) is a logo placed on PPE and medical devices to show they conform to the requirements in the regulations. It shows that the device is fit for its intended purpose stated and meets legislation relating to health and safety. It shows the product can be freely marketed anywhere in the EU.
- If manufacturers comply with certain European Standards (EN) it shows compliance with the relevant parts of the regulations.

7. Does this mean that health and care organisations will receive PPE that is not CE marked? How can we tell if they have been approved by the MHRA, HSE, or a Notified Body as being safe to use if they are not CE marked?

- Yes. In current circumstances the requirement for conformity assessment and CE marking has been relaxed subject to HSE, the market surveillance authority for PPE, agreeing that products without a CE mark can enter supply for healthcare use only. HSE has a process for assessing products and either agreeing their supply or directing that products cannot be released. All products supplied through the central NHS supply chain will have been agreed.
- It is feasible the PPE will itself come with written notification of the purposes for which it can be used without having a CE mark in place.

8. How long will the essential technical requirements last/be in place?

- These requirements will apply only during the continuation of the pandemic in the UK to ensure the ongoing and rapid provision of PPE.
- PPE allowed under the regulatory easement is only allowed to be used whilst the easement is in place and will have to be removed from supply when it is no longer being used as PPE for COVID-19.

9. Who do the essential technical requirements apply to?

- This essential technical requirements and supporting process applies to all manufacturers, suppliers, distributors and agents in the UK and overseas wishing to support the UK health and social care response to the pandemic including through the establishment of new domestic and international contracts where their product does not have a CE mark or the manufacturer wishes to propose the alternative use of an existing CE marked product against the relevant legislation.