HM Government

v1 – 05/05/20

User Guidance - Essential Technical Requirements for Personal Protective Equipment

Guidance on How to Present for Approval

The essential technical requirements for Personal Protective Equipment (PPE) have been developed by the Health and Safety Executive (HSE) and the Medicines and Healthcare Products Regulatory Agency (MHRA) on behalf of NHSE/I to ensure the rapid production of critical PPE for UK health and social care workers.

PPE, including where a medical device, and the associated essential technical requirements are clearly defined in the 'Essential Technical Specifications' document.

The Government is committed to facilitating the rapid production of PPE within the UK to ensure health and social care workers across the system have the critical equipment which they require, in the right quantity and at the right time including in light of limitations on international production and imports.

In addition to importing PPE where available, the Government is working with UK industry to actively consider options to turn on UK-centric manufacturing.

To enable this manufacturing to proceed at pace, the Government has been working with regulators – the MHRA and the HSE – to ensure essential technical requirements are in place and that there is a clear process to secure regulatory approval for sale of PPE produced against these which does not involve the normal process of CE marking.

The requirements are based on World Health Organisation guidance and PPE produced under this approach will not present a risk to patient or health and social care professionals' safety or well-being.

These standards will apply only during the continuation of the pandemic.

Who Does This Process Apply to?

This process applies to all manufacturers, suppliers, distributors and agents in the UK and overseas wishing to support the UK response to the pandemic including through the establishment of new domestic and international contracts where you do not have a CE

mark or wish to propose the alternative use of an existing CE marked product against the relevant legislation.

For those who have already submitted their interest to support the Covid-19 response, the process will also apply in respect of regulatory approvals and the required supportive evidence. However, there is no need to re-submit your interest at this time. The central purchasing team will make proactive contact to you as part of its review of all proposals received to date.

Summary of Process

Stage 1 – Submission of Proposal and Supporting Evidence by Manufacturer

- A Manufacturer wishes to support the UK pandemic response by producing PPE within the UK or overseas.
- The Manufacturer considers they can meet the essential technical requirements (Table 1 and 2 – page 5 of 'Essential Technical Specifications' document) for the relevant PPE but do not have a CE mark or, in relation to an existing CE marked product, wishes to propose an alternative use of that product against the essential technical requirements.
- To register an initial submission the manufacturer should visit the following link where they can submit details of their offer to support Covid-19:

  https://www.gov.uk/coronavirus-support-from-business

- The Manufacturer will then be asked to complete an online submission template when your initial submission has been registered. This asks key questions which require a response from the manufacturer to enable progress.
- The Manufacturer should upload the relevant information required to support their proposal to manufacture PPE or for the alternative use of existing CE marked PPE, including where a medical device.
- The Manufacturer should upload the relevant information to support the required regulatory decision.

Stage 2 – Consideration of Submission and Supporting Evidence by Regulator

- Ineligible submissions, for example where the required information is not provided or where the assurance of claimed compliance with the technical requirements cannot be verified, will be rejected.

- Further information will be directly requested of the manufacturer, where required, to support viable submissions.
- Where the essential technical requirements appear to be met/acceptable an application will be submitted to the appropriate regulator for decision.

    - For Medical Devices this is via the Medicines and Healthcare Products Regulatory Agency for a derogation consideration.

    - For technical assessment as non-surgical PPE this needs to go to Health and Safety Executive Technical team for agreement that an item can enter the supply chain.

- The authorisation to produce will be considered and, if appropriate, approved by HSE and/or MHRA. The Regulators will engage with each other and relevant government departments as required to ensure appropriate consideration.
- Where the essential technical requirements are met on the basis of claimed equivalence, for example the product has been approved against FDA or other international regulatory standards, the item will still require regulatory approval to confirm that equivalence before any purchasing can be authorised.
- Notification of this decision and authority to produce will be issued by the Regulator directly to the legal manufacturer/applicant and notified to the centralised procurement process.
- Notification of a decision to reject will be issued by the Regulator directly and notified to the centralised procurement process.

Stage 3 – Procurement of Approved PPE

- Centralised procurement for PPE will engage with the manufacturer on the contractual provisions, quantity, sizes and costs of PPE.
- Centralised procurement will track production and co-ordinate delivery of PPE to agreed storage facilities.
- Centralised procurement, on receipt, will standards check the PPE and deliver to the appropriate healthcare setting.
- Centralised procurement will ensure relevant payments are issued to the manufacturer.