Department of Health & Social Care

08.10.2021

Important Customer Notice

Communication to clarify the Transparent Mask position

Transparent Mask and model "ClearMask™" clarification

Issue:

ClearMask™

The ClearMask™ is a specific trade-marked product and there are many other transparent masks on the market.

- In October 2020, the DHSC procured 250,000 of model "ClearMask™" manufactured by ClearMask in the USA, this specific product was provided following an easement granted by the HSE for splash protection, as this mask did not provide filtration. There was a caveat within the communication letter released with the mask that they were not to be used in surgical settings, or surgical/invasive procedures, or where a Type IIR FRM would usually be worn, because filtration is required.
- This communication has more recently been referenced by some procurement leads and CCGs who consider it is applicable to all other models of transparent masks, even if they meet the new minimum specification detailed below. Also based on this communication has led to confusion for users who are being advised all transparent masks cannot be used in clinical settings. Communications about the ClearMask™ product only relate to this product and do not apply to other transparent masks. Any other masks needed to individually be assessed, as to the protection they provide and where they are suitable to used.

Transparent Mask

- Please be advised that in line with the discussions with the National IPC contacts, that only transparent masks that meet:
  - the Transparent Mask Minimum Specification Transparent face mask technical specification - GOV.UK (www.gov.uk) and/or holds a CE / UKCA / UKNI mark
  - or has been given a MHRA exceptional use authorisation if the mask is marketed as a medical device (also called a derogation)

can be used in in accordance with the masks intended purpose of use in appropriate clinical settings, where previously a Type IIR would have been worn, but there is a need for a transparent mask.

Transparent Mask testing requirements

- A transparent face mask working group was set up by NHS England and NHS Improvement. They produced a new technical specification which gives testing, design and performance requirements for single-use transparent face masks which are intended to provide comparable protection to that of a Type IIR mask. The transparent mask technical specification has been published online at: Transparent face mask technical specification - GOV.UK (www.gov.uk)
- Annex A of the specification explains the mechanisms of action of non-transparent medical masks and explores how similar mechanisms of action may be achieved with transparent masks.
- At present (and to the best of our knowledge), there have been no CE /UKCA/UKNI marked transparent face masks which have also passed the BS EN14683:2019 standard **in full**, hence the new technical specification.
- To-date two masks have been through the Technical Assurance review process, but both will need to resubmit for further review following feedback from the reassessment undertaken by Technical Assurance. The failings are either the testing documentation or not complying with the EHSR, or both.
- Organisations are at liberty to undertake their own due diligence and assure themselves a product is fully compliant with the transparent mask technical specification, as well as the EHSR prior to procurement, or they can forward them to the Reuse, Innovation & Sustainability (RIS) team at:

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- Masks complying with this technical specification cannot be referred to as Type IIR masks, as that term is defined in BS EN 14683:2019 and is reserved for products meeting the definition of a medical device, that also complies wholly with the requirements for Type IIR masks in that standard. Masks complying with this technical specification may however meet some of the requirements of BS EN 14683:2019. The specification has been written to meet a demonstrated demand for transparent face masks at the time of writing (spring 2021), and it is acknowledged that further revision may be necessary.
- Compliance with this specification cannot be used as a presumption of conformity with the corresponding essential requirements of any relevant regulations which may apply to transparent face masks. Other technical solutions may also demonstrate the safety and performance of transparent face masks and as such only forms one part of the evidence a manufacturer must hold to show the mask is fit for purpose.
- MHRA has published regulatory guidance on transparent face masks, including its position on labelling of transparent masks that are medical devices, if the transparent mask product is intended to be marketed as a medical device.
- Due diligence checks are still required within procurement checks even if:
  - CE, UKCA or UKNI mark affixed
  - MHRA medical device registration obtained (noting grace periods)

If you have any further questions, please send them to: england.pperis@nhs.net

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