Note regarding the use of ClearMasks – this has been agreed with the Health Safety Executive

Dear colleague,

The Department of Health & Social Care has purchased a number of *ClearMasks*^[1] for use in your organisation. Supplies of these are being manufactured rapidly but for the time being their use should be targeted in your organisation to where they will support patients, service users and staff.

Where can I use a ClearMask?

The *ClearMask* has a clear front, making the mouth and face visible to facilitate communication with service users who rely on lip-reading and use facial expression to support communication; this includes people who are d/Deaf, have a learning disability, autism and dementia.



The *ClearMask* face mask provides splash protection for the wearer in the same way that a type IIR surgical face mask does:

https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control. However, since the product has not been tested by regulators in the same way as a type IIR or type II surgical face mask, to show protection from the wearer to the patient,^[2] health and social care providers **must risk assess** the appropriate use of the product.

They should not be used:

- in the surgical/operating setting or for surgical/invasive procedures;
- where there is excessive splashing or spraying of body fluids (as potential splash-back from the impervious front);
- as an alternative to a filtering face-piece respirator, which is worn to protect the worker during aerosol generating procedures.

The ClearMask is a 'single use' product and should not be reused (https://www.theclearmask.com/user-manual).

Users should follow guidance on donning and doffing personal protective equipment (PPE) (https://www.gov.uk/government/publications/covid-19-personal-protective-equipment-use-for-non-aerosol-generating-procedures).

Approval for use of ClearMask face masks

ClearMask face masks are approved by the Health and Safety Executive (HSE) for use during the COVID-19 pandemic under the essential technical specification guidance (https://www.gov.uk/government/publications/technical-specifications-for-personal-protective-equipment-ppe).

Upon reviewing the *ClearMask* product documentation and assessing the intended use of *ClearMask* against the essential health and safety requirements of the EU

^[1] Distributed by ClearMask, LLC, 900 E. Fayette St., PO Box 22493, Baltimore, MD 21203, USA

^[2] The <u>PPE Ensemble Guidance</u> details where Type II and Fluid Resistant Type IIR surgical masks are typically used. *ClearMask* face masks have not been assessed for bacterial filtration efficiency, to determine source protection from the wearer to the patient, as a surgical mask. *ClearMask* does however protect the wearer from splashes in the same way that a Fluid Resistant Type IIR surgical mask does.

PPE regulation, the HSE has approved the availability of *ClearMask* face masks via NHS Supply Chain for use in healthcare settings as an item of PPE to protect the wearer.

Please note: ClearMask face masks are not currently CE marked which is why HSE approval was sought.

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