# 

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N Small

# ClearMask

Q: Can ClearMask be used where Type II surgical face mask is recommended by UK / 4 nations IPC guidance?

**Conclusion**: MHRA agree with HSE position.

In general, it is acting only as a fluid shield for the mouth and nose to provide splash resistance. It is not claiming or has any evidence of any other properties that are comparable to a medical face mask.

In particular an absence of properties as a barrier to bacterial penetration to *limit* the transmission of infective agents from staff to patients in a medical setting.

MHRA see no evidence or claim that in the context of C-19, it will be acceptable to use for ‘impatient care to any individuals in the extremely vulnerable group undergoing shielding’. Unless the group has obtained other evidence or has formed a decision based on a risk assessment of all available evidence and considering it the benefits outweigh the risks.

**Recommendation:**

1. Consult with the manufacturer on content of NHS letter to ensure its use in C-19 context remains within the claims/intended use of the legal manufacturer.

2. The NHS I letter has tracked changes to consider (below) . It is not clear what protection the mask is giving as a replacement for Type IIR medical face masks in the scenarios it is recommended for (to treat patients with possible or confirmed cases) - other than splash resistance.



**Assessment**

- Not CE marked under any regulations. The claim HSE has granted regulatory flexibility with conditions

- Manufacturer states use of these masks in “….*surgical setting or where significant exposure to liquid bodily or hazardous fluids may be expected, in a clinical setting where the infection risk through inhalation exposure is high.. is* ***not*** *recommended*”

- Claims – block the transfer of aerosols, fluids and sprays using an anti-fogging plastic barrier.

- MHRA see no data to support claim it blocks transfer of aerosols

- No claim by manufacturer that is performs similar to a medical face mask (no filter media – just plastic shield and [looser] fitting sides)

- Technical information

1. splash resistant (Level 3/160mmHg - comparable with Type IIR splash property only (>120mmHg)).

2. No filtration efficiency claimed/tested as ‘no air flow’ *through* plastic barrier (but air flow around sides as not as close fitting as a medical face mask - but not tight fitting as respirator)

3. No differential pressure testing (breathability). Not close fitting as a medical mask – comfort issue over time. Fogging may occur over time. However, the claim is that it is anti-fogging.

- Latex free



HSE position statement:

“The ClearMask product can be allowed into the NHS supply chain for use as PPE in healthcare for the treatment of COVID-19, however, the limitations of use are to be made clear (i.e. that this product:

• should not be used in a surgical setting;

• has not been assessed for bacterial efficiency to protect the patient from the worker and should not therefore be used in place of a Type II surgical mask to protect vulnerable asymptomatic patients; and

• is not an FFP3 respirator to protect the worker during Aerosol Generating Procedures).

This product can only be used for the duration of the COVID-19 outbreak, unless the product gains CE marking.

If the manufacturer intends this to be used to protect the patient in place of a Type II surgical mask, then they must seek MHRA agreement.

Therefore, this is quite a limited use and in practical terms means it can only be used as a replacement for a Type IIR in the PPE Ensemble and not for any other purpose. This is to protect the wearer as it offers equivalent splash protection to a Type IIR.”





