



02 June 2021

Dear Colleague,
Full Support Healthcare Easimask FSM25

This is an important notice relating to the delivery of Full Support Healthcare Easimask FSM25 (SKUBWM536) to your organisation. In some cases, you will notice that the label on the inner carton does not indicate the type (Type IIR) and some do not bear the expected CE mark. However, we can confirm that these have been approved for use as Type IIR face masks.

What checks have been done?

To meet current supply needs, the Medicines and Healthcare products Regulatory Agency (the medical device regulator) has approved release of this particular stock following a review of the available documentation provided by Full Support Healthcare. This includes confirmation that:

1. these face masks meet the standards claimed by the manufacturer; BS EN 14683 for Type IIR medical face masks
2. they have received an exceptional use (derogation) approval from MHRA following a robust review of the data, as this particular stock does not hold a CE mark (MHRA authorisation ref DEU/004/2021/002)

I have attached images of the packaging in the Annex below.

Where can I use them?

Use surgical/medical face masks of Type IIR standard (or equivalent) as part of the PPE ensemble for use against COVID-19 as per the gov.uk PPE guidance:

<https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control/covid-19-personal-protective-equipment-ppe>

Action:

Share this letter with all service providers that receive these products, particularly if the masks are removed from its outer/shelf box.

Moira Philpott – Chair – Decision Making Committee

Annex 1 - Full Support Healthcare Easimask- FSM25



Department
of Health &
Social Care

