

Safety Action Notice

Reference **SAN(SC)21/05**Issued **24 February 2021**Review Date **24 February 2022**

Fang Tian FT-045A FFP3 respirators supplied by Polyco Healthline, product code BWM541

Summary

The Department of Health and Social Care (DHSC) in England is investigating to verify that Fang Tian FT-045A FFP3 respirators meet DHSC's specification for FFP3 respirators. Users have been advised to stop using the product while the investigation is ongoing

Action

- Health board acute and primary care services are not required to take any action on this notice.
- Local authorities and contractors should:
 - Stop using the product
 - quarantine any stock
 - notify any organisations they have provided with this mask through mutual aid.
 - Contact Polyco Healthline (Enquiries) for information on whether and when affected products can be released from quarantine and returned to use.
 - Report adverse incidents to local incident management systems and to [IRIC](#).

Problem / background

The Department of Health and Social Care (DHSC) in England has issued information on Fang Tian FT-045A FFP3 respirators (see annexe). It has been suggested these products may not meet DHSC's essential technical specification for FFP3 masks. DHSC is therefore investigating to verify that this mask meets the necessary standards.

While this process is ongoing, DHSC has paused distribution pending further decisions once its investigation has concluded. In the meantime, users have been advised to stop using the product for the time being, quarantine any stock and notify any organisations they have provided with this mask through mutual aid.

Within Scotland, all FFP3 masks are procured by NSS National Procurement on behalf of territorial health boards. This arrangement is tightly controlled and it covers acute and primary care including GPs, dentists and optometrists. NSS National Procurement has confirmed that affected respirators have not been supplied in Scotland. This notice has therefore been issued on a precautionary basis to local authorities and contractors.

Supplier contacts

Polyco Healthline, South Fen Business Park, South Fen Road, Bourne, PE10 0DN
0333 320 8550 customer.services@polycohealthline.com

Suggested onward distribution

Adult Care Services
Care Homes
Children's Residential Services
Health, safety and wellbeing
Health & Safety
Home Care
Risk Management
Supplies/Procurement

Enquiries

Enquiries (and adverse incident reports) in Scotland should be addressed to:

Incident Reporting & Investigation Centre (IRIC)

NHS National Services Scotland
Gyle Square, 1 South Gyle Crescent, Edinburgh EH12 9EB
Tel: 0131 275 7575 Email: nss.irc@nhs.scot

Report options are available on the HFS website: [How to report an Adverse Incident](#)
Further information about reporting incidents can be found in [CEL 43 \(2009\)](#) or by contacting IRIC at the above address.

NHS National Services Scotland is the common name for the Common Services Agency for the Scottish Health Service. www.nhsnss.org
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Addressees may take copies for distribution within their own organisations

ANNEXE

Department
of Health &
Social Care

18th February 2021

Important Customer Notice – Immediate Action Required

Dear Colleague,

Manufacturer: Fang Tian FT-045A FFP3 masks
Supplier: Polyco Healthline
Product Code: BWM541

We have received information that suggests this item may not meet DHSC's essential technical specification for FFP3 masks. We are therefore investigating compliance with these standards to verify that this mask meets the necessary standards. Following information received from the NHS, we are also seeking to confirm the origin of manufacture.

We are undertaking a rapid review of which the regulators are aware. Meanwhile, we will pause distribution pending further decisions once our investigations have concluded.

We would ask that you check your stocks and stop using this product for the time being, and immediately quarantine any stock of this product you may have and cascade this message to any organisations you make have provided with this mask through mutual aid. Please see product and packaging images attached at **Annex A**.

Please be assured that we are working with regional teams and providers to fit test staff to alternative models and provide of them with alternative masks in the quantities needed. We have a good supply of other FFP3 masks. If you require further urgent fit testing support, please contact your regional fit test project manager listed at **Annex B**.

The safety of all frontline staff is our top priority. We have commissioned independent testing and will communicate with you shortly about the outcome of this.

Action Required

Review your stocks of FFP3s and identify whether you have any of the Fang Tian FT-045A FFP3 masks. If you have, these should be immediately quarantined. You should also be advised that some of these masks may have been delivered in boxes with the product marked as FT-045.

If you have further questions about this issue, please contact ppe.complaintsandenquiries@nhs.net.

Further Actions

We have taken immediate actions to stop any further distribution of the Fang Tian FT045A FFP3 masks at this time, and will provide a further update once our investigations have concluded.

Yours faithfully,

Moira Philpott
Acting Chair, DHSC PPE Decision Making Committee



Department of Health & Social Care

Annex A: Product Images





Department
of Health &
Social Care

Annex B: Contact Numbers for National Fit Test Team

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