

Safety Information Message

Reference

SIM2111

Issued **26 October 2021**

Obisk Bluetree Type IIR Face Mask: MKTIIR0214 (tie back) and MKTIIR0199 (ear looped) - Quarantine

Summary

Obisk Bluetree face masks manufactured from July 2021 are labelled Type IIR. However, information received by the manufacturer indicates that the masks may not meet technical specifications for splash protection. Please note, any items with a manufacture date prior to July 2021 are not affected by this notice.

Action

- Refer to attached document from Department of Health & Social Care (England) for further details of affected products and implement the recommended actions.

Enquiries

Enquiries and adverse incident reports 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

For information on how to report an incident: [How to report an Adverse Incident](#)

General information about adverse incidents and safety alerts 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.

<https://www.nss.nhs.scot/>

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Date: 22/10/2021

Important Customer Notice- Quarantine and Recall

Dear Colleague

Obisk Blue Tree Face Type IIR mask - MKTIIR0214 (tie back) and MKTIIR0199 (ear looped). Batch/LOT numbers:

- 101000345
- 101000346
- 101000348
- 101000349
- 101000350

Our records show that may you have received these items since July of this year. Please note, any items with a manufacture date prior to July 2021 are not affected by this notice.

These are labelled Type IIR, however information received by the manufacturer indicates that the masks **may not** meet technical specifications for splash protection. This affects only the batch numbers stated above.

The manufacturer has submitted a report to the MHRA.



MKTIIR0199



MKTIIR0214



Department
of Health &
Social Care



Indication of where to
locate LOT number on
inner box/ carton

Action Required

Pending further investigation, please do not use in clinical environments. Please conduct an immediate review of your mask stock, in order to identify if you have any of the affected products.

If you have any of these products, please inform the [redacted], quoting Ref: **Obisk Blue Tree Face Type IIR mask** and confirm the volume of product in stock by **15/11/21**. We will then give further instructions determined by service environment, please also let us know if replacement stock is required.

Further Actions

The manufacturer has instigated a full investigation, overseen by the regulator. Once we have further information, an update will be provided

Yours faithfully,

Moira Philpott
Chair Decision Making Committee

Notes for Scotland

Contact details above have been redacted as unsuitable for Scotland. Contact the manufacturer Bluetree Medical direct:

Email: report@bluetreemedical.co.uk
Phone: 0114 6970808