

**URGENT FIELD SAFETY NOTICE**

**Obisk Disposable Type IIR Surgical Masks**

**This document contains important information regarding the safe use of your goods.**

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important that you fully understand the implications of this communication. If you require any further clarification, or you need to contact us in relation to this communication please use the following contact details:

Email: [report@bluetreemedical.co.uk](mailto:report@bluetreemedical.co.uk)      Telephone: 0114 6970808

Dear Customer,

The purpose of this letter is to inform you that Bluetree Group has issued a field safety notice relating to Obisk Type IIR Masks. A problem has been identified with masks manufactured using a particular batch of material. The product meets the requirements for bacterial filtration efficiency, microbial cleanliness and breathability however it does not achieve the required splash resistance to be categorised as a Type IIR. As such it offers infection control equivalent to a Type II surgical mask with the breathability performance of a Type IIR.

**Description of the problem**

The main intended use of medical face masks is to protect the patient from infective agents and, additionally, in certain circumstances protect the wearer against splashes of potentially contaminated liquids. Although the masks affected achieve this main intended purpose, protecting the patient from infective agents, the batches identified below do not achieve the splash resistance required by the BS EN 14683:2019 standard to protect the wearer against potentially contaminated splashes.

As of 26<sup>th</sup> October 2021, there have been no reports of harm associated with this issue.

**Products affected**

Batches of the following products are affected by this Field Safety Notice:

Product Code	Product Description	Packaging	UDI-DI	Manufacture Date
OB11R	Obisk Disposable Type IIR Surgical Masks with Ear Loops	Supplied in boxes of 50 masks	05056423700060	July 2021
OB11RT	Obisk Disposable Type IIR Surgical Masks with Tie Backs	Supplied in boxes of 25 masks	05056423700220	July 2021

The following batches of the above products are affected:

Batch / Lot Number	Product Code
101000345	OB11R
101000346	OB11R
101000348	OB11R
101000349	OB11R
101000350	OB11RT
101000354	OB11R

The lot number can be found on the box, as pictured below.



### **Actions to be taken by the customer**

1. Review the content of this field safety notice.
2. Check your stock for the affected product code and lot number.
3. Isolate any affected stock to prevent it being used or distributed.
4. Communicate to all those who need to be aware within your organisation or any organisation that you may have distributed or forwarded the product to.
5. Complete the relevant sections of the response form located in the Annex of this Field Safety Notice to arrange product replacement by the 9<sup>th</sup> November 2021

**Corrective being taken by Bluetree**

This notice has been reported to the appropriate regulatory authority (MHRA) and our affected customers have been notified. The quality processes for this product have been reviewed and actions implemented to prevent this from being able to happen in the future.

We apologise for the inconvenience this may have caused and appreciate your understanding as we have taken this action in the interest of patient safety.

Sincerely,

Richard Crow

Head of Compliance

## Annex 1 – Response Form

This form must be completed and emailed to [report@bluetreemmedical.co.uk](mailto:report@bluetreemmedical.co.uk)

Please complete the table below indicating the quantity of affected product you currently stock, our team will contact you to arrange replacement and will supply an RMA number. If you do not have any affected stock, please indicate this in the check box below the form.

Product Details:

Lot Number	Quantity of Masks Requiring Replacement
101000345	
101000346	
101000348	
101000349	
101000350	
101000354	

We confirm that do not have any of the affected product.

We confirm that we have received and understood this Field Safety Notice and we have implemented all necessary actions to minimise the risks outlined in the notice.

Organisation or Company \_\_\_\_\_

Address \_\_\_\_\_

Contact Number: \_\_\_\_\_

Email Address: \_\_\_\_\_

Name of Person Receiving this \_\_\_\_\_

Notice: Position:

Signature:

Date: