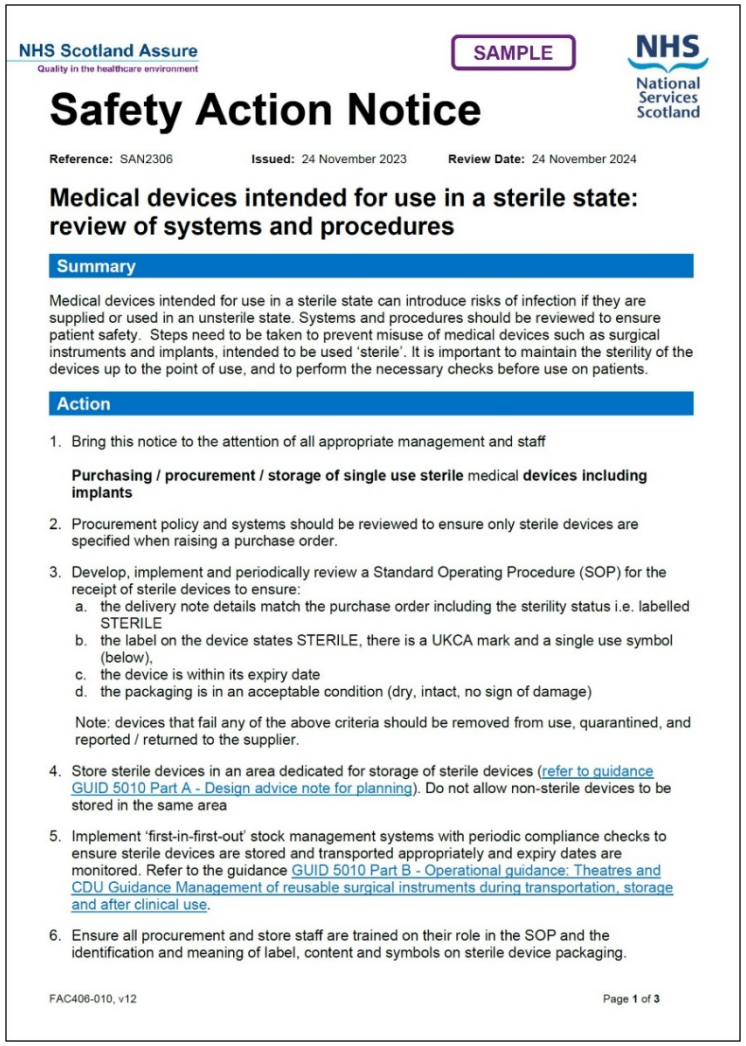
Scottish alert formats



NHS Scotland Assure
Quality in the healthcare environment

SAMPLE

NHS National Services Scotland

Safety Action Notice

Reference: SAN2306 **Issued:** 24 November 2023 **Review Date:** 24 November 2024

Medical devices intended for use in a sterile state: review of systems and procedures

Summary

Medical devices intended for use in a sterile state can introduce risks of infection if they are supplied or used in an unsterile state. Systems and procedures should be reviewed to ensure patient safety. Steps need to be taken to prevent misuse of medical devices such as surgical instruments and implants, intended to be used 'sterile'. It is important to maintain the sterility of the devices up to the point of use, and to perform the necessary checks before use on patients.

Action

1. Bring this notice to the attention of all appropriate management and staff

   Purchasing / procurement / storage of single use sterile medical **devices including implants**

2. Procurement policy and systems should be reviewed to ensure only sterile devices are specified when raising a purchase order.

3. Develop, implement and periodically review a Standard Operating Procedure (SOP) for the receipt of sterile devices to ensure:
   a. the delivery note details match the purchase order including the sterility status i.e. labelled STERILE
   b. the label on the device states STERILE, there is a UKCA mark and a single use symbol (below),
   c. the device is within its expiry date
   d. the packaging is in an acceptable condition (dry, intact, no sign of damage)

   Note: devices that fail any of the above criteria should be removed from use, quarantined, and reported / returned to the supplier.

4. Store sterile devices in an area dedicated for storage of sterile devices (refer to guidance GUID 5010 Part A - Design advice note for planning). Do not allow non-sterile devices to be stored in the same area

5. Implement 'first-in-first-out' stock management systems with periodic compliance checks to ensure sterile devices are stored and transported appropriately and expiry dates are monitored. Refer to the guidance GUID 5010 Part B - Operational guidance: Theatres and CDU Guidance Management of reusable surgical instruments during transportation, storage and after clinical use.

6. Ensure all procurement and store staff are trained on their role in the SOP and the identification and meaning of label, content and symbols on sterile device packaging.

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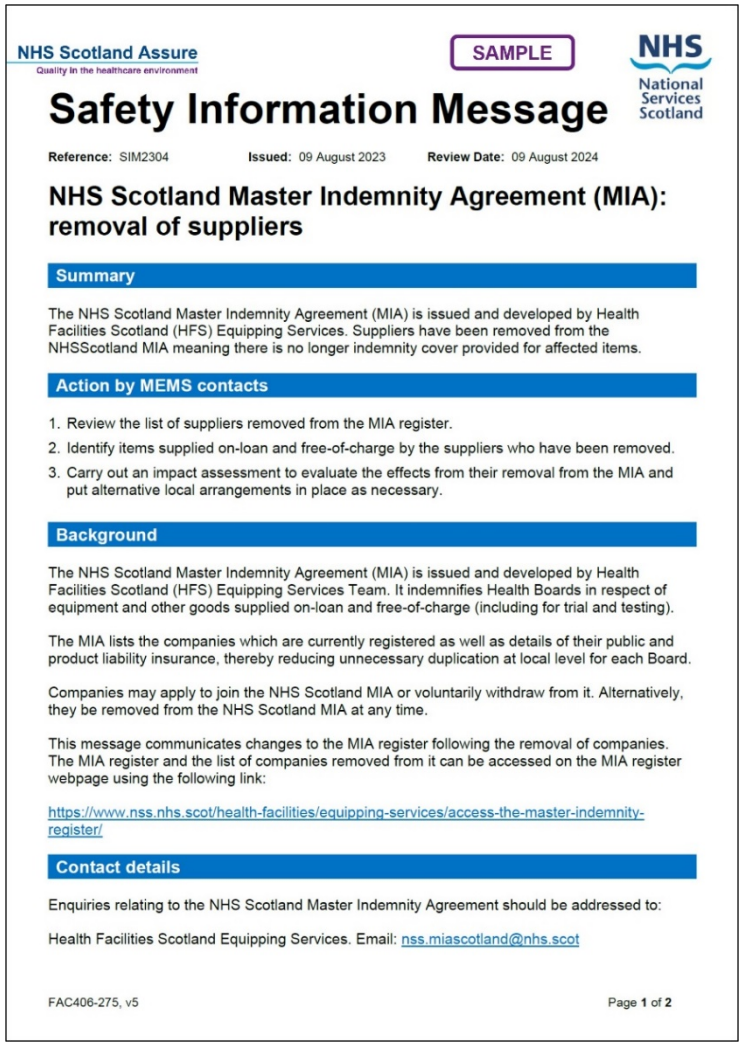

NHS Scotland Assure
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SAMPLE

NHS National Services Scotland

Safety Information Message

Reference: SIM2304 **Issued:** 09 August 2023 **Review Date:** 09 August 2024

NHS Scotland Master Indemnity Agreement (MIA): removal of suppliers

Summary

The NHS Scotland Master Indemnity Agreement (MIA) is issued and developed by Health Facilities Scotland (HFS) Equipping Services. Suppliers have been removed from the NHSScotland MIA meaning there is no longer indemnity cover provided for affected items.

Action by MEMS contacts

1. Review the list of suppliers removed from the MIA register.
2. Identify items supplied on-loan and free-of-charge by the suppliers who have been removed.
3. Carry out an impact assessment to evaluate the effects from their removal from the MIA and put alternative local arrangements in place as necessary.

Background

The NHS Scotland Master Indemnity Agreement (MIA) is issued and developed by Health Facilities Scotland (HFS) Equipping Services Team. It indemnifies Health Boards in respect of equipment and other goods supplied on-loan and free-of-charge (including for trial and testing).

The MIA lists the companies which are currently registered as well as details of their public and product liability insurance, thereby reducing unnecessary duplication at local level for each Board.

Companies may apply to join the NHS Scotland MIA or voluntarily withdraw from it. Alternatively, they be removed from the NHS Scotland MIA at any time.

This message communicates changes to the MIA register following the removal of companies. The MIA register and the list of companies removed from it can be accessed on the MIA register webpage using the following link:

https://www.nss.nhs.scot/health-facilities/equipping-services/access-the-master-indemnity-register/

Contact details

Enquiries relating to the NHS Scotland Master Indemnity Agreement should be addressed to:

Health Facilities Scotland Equipping Services. Email: nss.miascotland@nhs.scot

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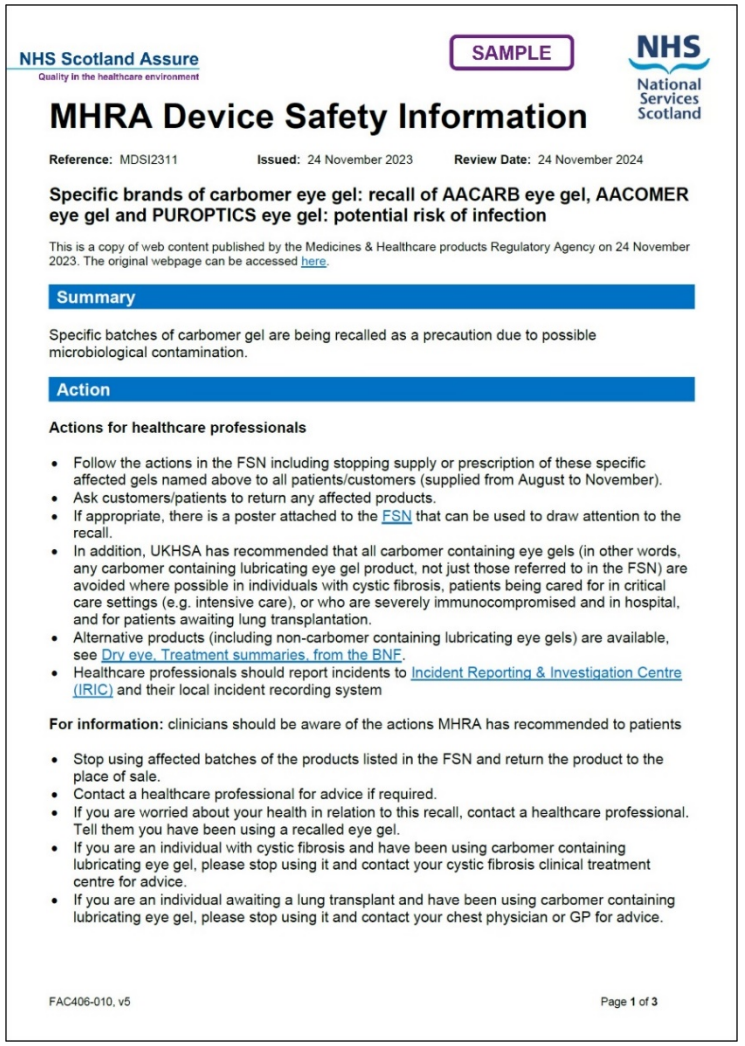

NHS Scotland Assure
Quality in the healthcare environment

SAMPLE

NHS National Services Scotland

MHRA Device Safety Information

Reference: MDSI2311 **Issued:** 24 November 2023 **Review Date:** 24 November 2024

Specific brands of carbomer eye gel: recall of AACARB eye gel, AACOMER eye gel and PUROPTICS eye gel: potential risk of infection

This is a copy of web content published by the Medicines & Healthcare products Regulatory Agency on 24 November 2023. The original webpage can be accessed here.

Summary

Specific batches of carbomer gel are being recalled as a precaution due to possible microbiological contamination.

Action

Actions for healthcare professionals

- Follow the actions in the FSN including stopping supply or prescription of these specific affected gels named above to all patients/customers (supplied from August to November).
- Ask customers/patients to return any affected products.
- If appropriate, there is a poster attached to the FSN that can be used to draw attention to the recall.
- In addition, UKHSA has recommended that all carbomer containing eye gels (in other words, any carbomer containing lubricating eye gel product, not just those referred to in the FSN) are avoided where possible in individuals with cystic fibrosis, patients being cared for in critical care settings (e.g. intensive care), or who are severely immunocompromised and in hospital, and for patients awaiting lung transplantation.
- Alternative products (including non-carbomer containing lubricating eye gels) are available, see Dry eye, Treatment summaries, from the BNF.
- Healthcare professionals should report incidents to Incident Reporting & Investigation Centre (IRIC) and their local incident recording system

For information: clinicians should be aware of the actions MHRA has recommended to patients

- Stop using affected batches of the products listed in the FSN and return the product to the place of sale.
- Contact a healthcare professional for advice if required.
- If you are worried about your health in relation to this recall, contact a healthcare professional. Tell them you have been using a recalled eye gel.
- If you are an individual with cystic fibrosis and have been using carbomer containing lubricating eye gel, please stop using it and contact your cystic fibrosis clinical treatment centre for advice.
- If you are an individual awaiting a lung transplant and have been using carbomer containing lubricating eye gel, please stop using it and contact your chest physician or GP for advice.

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