



Convatec Reference: 2288160- Natura+ - Leakage at the bottom part of the pouch

Notice Type: New

Date: Jul-2025

URGENT: VOLUNTARY FIELD SAFETY NOTICE

Natura+

To: Affected Customers / Consignees,

Convatec Ltd is conducting a Field Safety Corrective Action (removal) for Natura +.

| Item Number (ICC Code) | Lot Number | UDI |
|------------------------|------------|----------------|
| 416417 | 4J01987 | 00768455171156 |

This Field Safety Corrective Action has been initiated due to a leakage problem occurring due to the fault/hole at the bottom part of the pouch.

To date, 7 complaints have been received of leakage from the outline weld near the tail. No harm has been reported for these complaints and no damage to property. Our records indicate that you may have received one or more of the affected products. The affected units were manufactured on:

Item Number – 416417 (Lot 4J01987) - manufacture date: 10-SEP-2024

Immediately examine your inventory and quarantine product subject to this communication.

In addition, if you have further distributed this product, please identify your customers, and notify them at once of this product recall.

Your notification to your customers may be enhanced by including a copy of this recall notification letter.

Your assistance is required to prevent continued distribution or use of defective products.

Please follow the “**Your Responsibilities**” section and ensure to complete the survey in the email as soon as possible or within 30-days of receipt.



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YOUR RESPONSIBILITIES

1. Review this notification and ensure that all relevant stakeholders are aware of the contents.
2. Immediately locate and quarantine affected product in your inventory.
3. Complete the Survey **FSN Response – Natura+ Recall (Ref: 2288160)** – link in the email notification.
4. Immediately destroy all affected product, ensuring you Complete Convatec Certificate of Destruction as evidence to support reconciliation and regulatory reporting.
5. Your account will be credited for all destroyed product upon receipt of the survey and a Certificate of Destruction. Please ensure your account number is correctly identified in the Survey and on the Certificate of Destruction.

OTHER INFORMATION

The Competent (Regulatory) Authority of your country has been informed about this communication to customers as required. Please keep Convatec informed of any adverse events associated with this product.

TRANSMISSION OF THIS COMMUNICATION

- This notice needs to be disseminated on to all who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.
- Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.
- Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Any further questions please contact Convatec Recall Coordinator fsca-id@convatec.com.

Thank you for your assistance. We regret any inconvenience caused by this action.

Sincerely,