# URGENT FIELD SAFETY NOTICE
## ESENTA™ Stomahesive Paste

**Issue Date:** Oct-2026
**Reference:** TW-3258356
**Subject:** Voluntary Field Action for Specific Lots

Dear Customer,

Convatec is conducting a voluntary field action (removal) of specific lots of **ESENTA™ Stomahesive Paste** due to a quality related issue involving the potential presence of foreign matter within the product. According to our records, your organisation may have received affected lots of ESENTA™ Stomahesive Paste. Immediate action is required to identify, quarantine, and discontinue further distribution or use of affected product.

### Affected Product *(Globally)*

| Product Code | Affected LOTs | Product Description | Primary UDI |
|---|---|---|---|
| 1729233 | 6C03499 | ESENTA SHESIVE PASTE(1X60GTUBE) | 00768455169900 |
| 1729236 | 5K03776<br>5L00431<br>5L00432<br>5L02607<br>5M02351<br>5M03521<br>6A04022<br>6E01525<br>6E05356<br>6E05929 | ESENTA SHESIVE PASTE(1X56.7GTUBE) | 00768455169931 |
| 1739996 | 5J04201<br>5K00858<br>5L00433<br>5L02930<br>6A03082<br>6B00827<br>6E01386<br>6E03598 | ESENTA S/HESIVE PASTE 1TUBEX56.7G | 00768455209255 |
| 1739997 | 6C03991 | ESENTA S/HESIVE PASTE 1TUBEX60G | 00768455209262 |
| 1739998 | 6B00828<br>6C05168<br>6D02979 | ESENTA S/HESIVE PASTE 1TUBEX60G | 00768455209279 |
| 1739999 | 6A03083<br>6B00830<br>6D00838<br>6E01524 | ESENTA S/HESIVE PASTE 1TUBEX60G | 00768455209286 |
| 1740000 | 6A04010 | ESENTA S/HESIVE PASTE 1TUBEX60G | 00768455209293 |
| 1740002 | 6C03980<br>6D00839<br>6E03597 | ESENTA S/HESIVE PASTE 1TUBEX60G | 00768455209316 |
| 1740003 | 6E01523 | ESENTA S/HESIVE PASTE 1TUBEX60G | 00768455209323 |

Country specific affected product identification details provided in **Appendix 2** and product label provided in **Appendix 3.**

The affected lots of **ESENTA™ Stomahesive Paste** were distributed between **27-Jan-26 to 09-Sep-26** in Bahrain, Belgium, Bosnia, Croatia, Denmark, Estonia, Germany, Hungary, Iceland, Iran, Ireland, Israel Kenya, Lebanon, Lithuania, Luxembourg, Macedonia, Malta, Netherlands, Norway, Qatar, Romania, Serbia Slovenia, South Africa, Sweden, Switzerland, Tunisia, Turkey, UK, and UAE.

## Reason

Through routine complaint handling and quality monitoring activities, a product quality issue was identified involving the presence of foreign matter in certain units of **ESENTA™ Stomahesive Paste**.

Subsequent investigation determined that existing controls at a third-party manufacturing facility were not fully effective in preventing contamination of Convatec materials. As a result, there is the potential for foreign contamination of affected product lots listed within the scope of this notification.

Based on the investigation findings and as a precautionary measure to protect product quality and patient safety, Convatec is voluntarily recalling the affected lots of **ESENTA™ Stomahesive Paste.**

## Potential Risk

The presence of foreign matter in the affected product may impact product quality and intended performance. Potential adverse effects associated with the use of affected product may include local inflammatory response, minor infection, skin irritation, rash, mucosal irritation, or allergic reaction.

The quality defect may be detected through visual inspection prior to application or use.

To date, no adverse events related to this issue have been reported to Convatec. One (1) customer complaint involving foreign matter was received and led to the investigation and subsequent corrective action.

## Action Required

### Distributors & Healthcare Facilities

Take the following actions without undue delay;

- **Examine your inventory** and identify all affected product lots using the details provided in the enclosed Product Identification Table (**Appendix 2**).
- **Immediately quarantine and discontinue distribution, sale, transfer, and use** of all affected product to prevent further distribution or use.
- **Inform all appropriate personnel** within your organisation, including those responsible for inventory management, purchasing, distribution, and product use, of this recall action.
- **If you have distributed any affected product further,** immediately identify all customers who received the affected lots and notify them of this corrective action. A copy of this communication can be provided accompanied with a cover letter from your organisation. Maintain records of all customer notifications and provide confirmation of completion upon request.
- **Acknowledgement:** Please confirm receipt of this notice and your compliance with the required actions by completing and returning the enclosed acknowledgement form (**Appendix 1**) **to** European.CustomerSupport@convatec.com within 30-days.
- If affected product is identified within your inventory, Convatec will provide a **Certificate of Destruction (COD)** for completion.
- Following destruction, please **complete and return the signed Certificate of Destruction (COD)** to Convatec as evidence to support compliance with this action.

**Important:** If not Convatec, contact the supplier from whom the product was purchased to report any affected inventory and obtain instructions regarding product disposition.

## Healthcare Professionals

At this time, Convatec has not received reports indicating that patient intervention is required solely as a result of the issue described in this notification. Healthcare professionals should continue to use their clinical judgment when evaluating patients who may have been exposed to the affected device.

- Identify, quarantine, and dispose of all affected product.
- Discontinue use of affected product.
- Inform relevant staff members of this action.
- Report any adverse events or complaints associated with the affected device to Convatec and applicable regulatory authorities, as required.

## End Users / Patients

If you possess any affected **ESENTA™ Stomahesive Paste** identified in this notice **(Appendix 2)**:

- Stop using the product immediately.
- Set the product aside and do not use it.
- Contact your healthcare provider, supplier, pharmacy, or Convatec representative for further instructions.
- Retain the product and lot number information until you receive further guidance.

If you have used affected product and experience any unexpected symptoms, including irritation, rash, inflammation, signs of infection, or other concerning symptoms, contact your healthcare professional promptly.

## Convatec Sales Representatives

Please take the following actions immediately:

- Familiarize yourself with this recall notification and the affected lot numbers.
- Immediately stop distribution, and promotion of affected products.
- Review all personal stock, consignment stock, and demonstration kits.
- Complete the Response Form below **(Appendix 1)** and return to **European.CustomerSupport@convatec.com** within 30-days.
- Complete a certificate of destruction (COD) (provided in the email package) and return.
- Support customers in identifying affected product within inventory, where requested.
- Escalate all reports of complaints, quality concerns, potential adverse events, or customer questions through established Convatec processes.

## Corrective Action Being Taken by Convatec

Convatec has initiated this voluntary field action to remove affected product from the market to prevent potential safety concerns and product performance issues.

Appropriate corrective actions will be implemented to address and mitigate this issue, and to strengthen process controls, ensuring ongoing compliance with product quality and regulatory requirements.

We are working closely with our partner and customers to manage the situation effectively and to support customers in maintaining continuity of care and minimising potential disruption to patient treatment.

## Transmission of Notice & Reporting

- This notice must be shared with all individuals within your organisation who need to be informed, as well as any external organisations to whom the potentially affected devices may have been supplied or transferred.
- Please ensure continued awareness of this notice and the associated actions for an appropriate period, so that the corrective measures remain effective across your organisation.
- All device-related incidents or complaints should be reported to the manufacturer, distributor, or local representative. Such reporting provides essential feedback for ongoing safety monitoring.
- Please continue to inform Convatec of any adverse events associated with this product through your usual reporting channels.

### Reporting to Authorities

The appropriate local regulatory authorities have been notified of this action in accordance with applicable regulatory requirements.

## Contact information

**Customer Services & Replacement Product:** Appendix 4
**Response Form & Credits:** European.CustomerSupport@convatec.com
**Field Action Questions:** fsca-id@convatec.com

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Convatec remains committed to transparency, regulatory compliance, and delivering high-quality products
Thank you for your understanding and we apologise for any inconvenience this action may cause.

Sincerely,
Tara Turney

Signed by:
Tara Turney
Signer Name: Tara Turney
Signing Reason: I approve this document
Signing Time: Oct 7, 2026 | 10:24:06 PM BST
51FC49C4BB42442A94A091E31D53F71B

Senior Director
Regulatory Affairs

# URGENT FIELD SAFETY NOTICE

## APPENDIX 1: RESPONSE FORM

- *Immediately complete*
- *If you have no affected product a completed response form is still required*
- *Return the completed form via email* European.CustomerSupport@convatec.com

**Issue Date:** October 2026 **CVT Ref:** TW-3258356

**Original Notice:** X **Revised Notice:** N/A **Revision Number:** 1

| Invoice # | Sales Order # | Product Code | SAP Code | LOT# | Quantity Delivered |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

| | |
|---|---|
| **Account No:** | |
| **Business Name:** | |
| **Address:** | |

| Yes | No | Declaration | |
|---|---|---|---|
| ☐ | ☐ | I confirm receipt, understanding and acknowledgement of this action | |
| ☐ | ☐ | I have checked my inventory, and I have **no product on hand** | |
| ☐ | ☐ | I have checked my inventory, and **I have product on hand** | QTY |
| ☐ | ☐ | I have checked my inventory, quarantined, and disposed of affected inventory | |
| ☐ | ☐ | I have attached a Certificate of Destruction (COD) as requested evidence | |
| ☐ | ☐ | I have identified customers that received or may have received affected product | |
| ☐ | ☐ | I have informed the identified customers of this notification | Date Sent |

***NOTE: If the statements listed within the table are not applicable, mark as N/A***

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**Issue Date:** October 2026 **CVT Ref:** TW-3258356

**Original Notice:** X **Revised Notice:** N/A **Revision Number:** 1

# ACTION ACKNOWLEDGEMENT

| | |
|---|---|
| **NAME** | |
| **JOB TITLE** | |
| **SIGNATURE** | |
| **DATE** | |

# APPENDIX 2 – Product Identification Table

| Country | Product SAP Code | Product ICC Code | Lot Number | Date of Manufacture | Expiry Date |
|---|---|---|---|---|---|
| Bahrain | 1729236 | 183910 | 5L00431 | 04 November 2025 | 01 November 2030 |
| Belgium | 1739997 | 183910 | 6C03991 | 19 March 2026 | 01 March 2031 |
| | 1740002 | 183910 | 6E03597 | 18 May 2026 | 01 May 2031 |
| Bosnia | 1739998 | 183910 | 6C05168<br>6D02979 | 28 March 2026<br>16 April 2026 | 01 March 2031<br>01 April 2031 |
| Croatia | 1739998 | 183910 | 6B00828<br>6C05168<br>6D02979 | 03 February 2026<br>28 March 2026<br>16 April 2026 | 01 February 2031<br>01 March 2031<br>01 April 2031 |
| Denmark | 1729233 | 183910 | 6C03499 | 18 March 2026 | 01 March 2031 |
| Estonia | 1739998 | 183910 | 6B00828 | 03 February 2026 | 01 February 2031 |
| Germany | 1739999 | 183910 | 6A03083<br>6B00830<br>6D00838<br>6E01524 | 13 January 2026<br>03 February 2026<br>07 April 2026<br>07 May 2026 | 01 January 2031<br>01 February 2031<br>01 April 2031<br>01 May 2031 |
| Hungary | 1739998 | 183910 | 6B00828<br>6C05168<br>6D02979 | 03 February 2026<br>28 March 2026<br>16 April 2026 | 01 February 2031<br>01 March 2031<br>01 April 2031 |
| Iceland | 1729233 | 183910 | 6C03499 | 18 March 2026 | 01 March 2031 |
| Iran | 1729236 | 183910 | 5L00431<br>5L02607<br>5M02351<br>5M03521 | 04 November 2025<br>13 November 2025<br>11 December 2025<br>18 December 2025 | 01 November 2030<br>01 December 2030 |

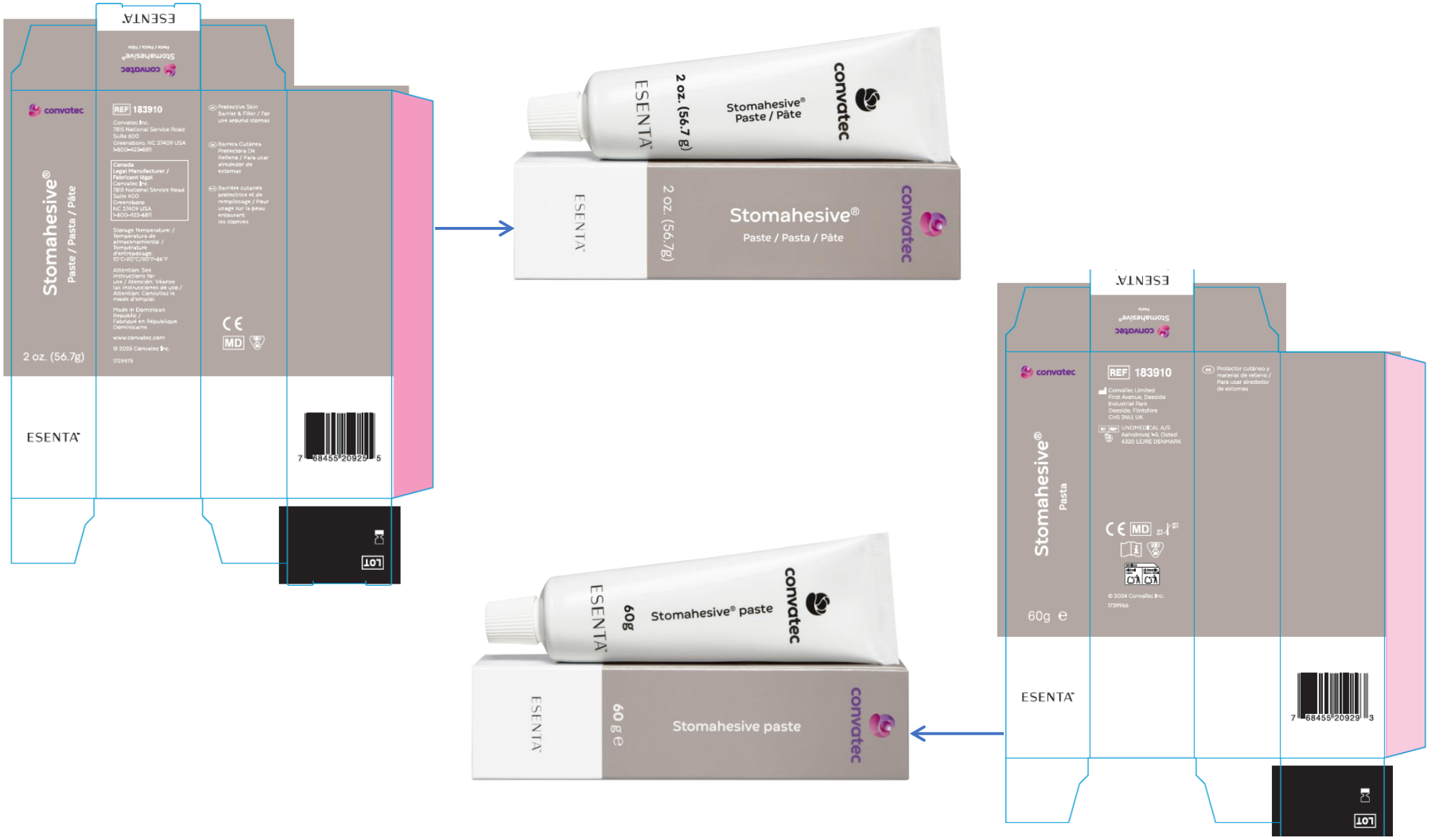
# APPENDIX 2 – Product Identification Table

| Country | Product SAP Code | Product ICC Code | Lot Number | Date of Manufacture | Expiry Date |
|---|---|---|---|---|---|
| Ireland | 1739999 | 183910 | 6E01524 | 07 May 2026 | 01 May 2031 |
| | 1740002 | 183910 | 6C03980<br>6E03597 | 19 March 2026<br>18 May 2026 | 01 March 2031<br>01 May 2031 |
| Israel | 1740002 | 183910 | 6C03980 | 19 March 2026 | 01 March 2031 |
| Kenya | 1729236 | 183910 | 5L00431<br>5M02351 | 04 November 2025<br>11 December 2025 | 01 November 2030<br>01 December 2030 |
| Lebanon | 1729236 | 183910 | 5M03521 | 18 December 2025 | 01 December 2030 |
| Lithuania | 1739998 | 183910 | 6B00828 | 03 February 2026 | 01 February 2031 |
| Luxembourg | 1739997 | 183910 | 6C03991 | 19 March 2026 | 01 March 2031 |
| Macedonia | 1739998 | 183910 | 6B00828 | 03 February 2026 | 01 February 2031 |
| Malta | 1740002 | 183910 | 6C03980<br>6D00839<br>6E03597 | 19 March 2026<br>07 April 2026<br>18 May 2026 | 01 March 2031<br>01 April 2031<br>01 May 2031 |
| Netherlands | 1739999 | 183910 | 6B00830 | 03 February 2026 | 01 February 2031 |
| | 1740002 | 183910 | 6C03980<br>6D00839<br>6E03597 | 19 March 2026<br>07 April 2026<br>18 May 2026 | 01 March 2031<br>01 April 2031<br>01 May 2031 |
| Norway | 1729233 | 183910 | 6C03499 | 18 March 2026 | 01 March 2031 |
| Romania | 1739998 | 183910 | 6C05168 | 28 March 2026 | 01 March 2031 |

# APPENDIX 2 – Product Identification Table

| Country | Product SAP Code | Product ICC Code | Lot Number | Date of Manufacture | Expiry Date |
|---|---|---|---|---|---|
| Serbia | 1739998 | 183910 | 6C05168<br>6D02979 | 28 March 2026<br>16 April 2026 | 01 March 2031<br>01 April 2031 |
| Slovenia | 1739998 | 183910 | 6B00828<br>6C05168<br>6D02979 | 03 February 2026<br>28 March 2026<br>16 April 2026 | 01 February 2031<br>01 March 2031<br>01 April 2031 |
| South Africa | 1729236 | 183910 | 5L00431<br>5M02351 | 04 November 2025<br>11 December 2025 | 01 November 2030<br>01 December 2030 |
| Sweden | 1729233 | 183910 | 6C03499 | 18 March 2026 | 01 March 2031 |
| Switzerland | 1739999 | 183910 | 6A03083<br>6B00830<br>6D00838<br>6E01524 | 13 January 2026<br>03 February 2026<br>07 April 2026<br>07 May 2026 | 01 January 2031<br>01 February 2031<br>01 April 2031<br>01 May 2031 |
| Tunisia | 1729236 | 183910 | 5L00431 | 04 November 2025 | 01 November 2030 |
| Turkey | 1729236 | 183910 | 5L00431<br>5L02607<br>5M02351<br>6E01525 | 04 November 2025<br>13 November 2025<br>11 December 2025<br>07 May 2026 | 01 November 2030<br>01 November 2030<br>December 2030<br>01 May 2031 |
| | 1739998 | 183910 | 6B00828<br>6C05168 | 03 February 2026<br>28 March 2026 | 01 February 2031<br>01 March 2031 |
| | 1740002 | 183910 | 6D00839<br>6E03597 | 07 April 2026<br>18 May 2026 | 01 April 2031<br>01 May 2031 |
| United Kingdom | 1740002 | 183910 | 6C03980<br>6D00839 | 19 March 2026<br>07 April 2026 | 01 March 2031<br>01 April 2031 |
| UAE | 1729236 | 183910 | 5L00431<br>5M02351<br>6E05929 | 04 November 2025<br>11 December 2025<br>30 May 2026 | 01 November 2030<br>01 December 2030<br>01 May 2031 |

# APPENDIX 3 – Packaging Identification



## APPENDIX 4 – Contact Details

- Customer Services & Replacement Product

| Country | Email | Telephone |
|---|---|---|
| Bahrain | Export.CustomerService@convatec.com | N/A |
| Bosnia-Herz | | |
| Croatia | | |
| Estonia | | |
| Hungary | | |
| Iceland | | |
| Iran | | |
| Israel | | |
| Kenya | | |
| Lebanon | | |
| Lithuania | | |
| Macedonia | | |
| Malta | | |
| Qatar | | |
| Romania | | |
| Serbia | | |
| Slovenia | | |
| South Africa | | |
| Tunisia | | |
| Turkey | | |
| UAE | | |
| Belgium | be.klantenservice@convatec.com | N/A |
| Luxembourg | | 02 352 89 56 |
| Denmark | customerservicenordic@convatec.com | N/A |
| Norway | | 22-686095 |
| Sweden | | 042-332010 |
| Switzerland | CustomerServiceSwitzerland@convatec.com | 0800 162 4381 |
| Germany | de.kundenservice@convatec.com | 0800 162 4381 |
| Netherlands | nl.klantenservice@convatec.com | +31 348 436 987 |
| Ireland | uk.customerservice@convatec.com | N/A |
| UK | | 01244 284882 |