

Convatec Reference: TW-2555515
Issue Date: Feb-2026
Notice Type: New
Version: 1.0

Urgent Field Safety Notice

Esteem Body™

Dear Distributor / End-User,

Convatec is conducting a voluntary field safety corrective action (removal) for **specific lots of Esteem Body™ Drainable Large Pouches** due to a manufacturing variation affecting the drainable tail section, which may cause the pouch to leak during use. The affected product does not consistently meet our high standards or commitment to quality. Figure 1

Figure1



Figure 1 – Image of the affected pouch showing the drainable tail section where the manufacturing variation may occur

Product Information

Item Number	Brand Name	Lot/Batch	UDI-DI	Primary UDI
423642	ESTBODY DRN	5K04906	768455OST0038FL	00768455221257
423643	ESTBODY DRN	5K00011 5K00714 5K05142 5K05417 5K05418	768455OST0038FL	00768455221264
423644	ESTBODY DRN	5J02728	768455OST0038FL	00768455221271
423651	ESTBODY DRN	5M02908	768455OST0038FL	00768455221349
423653	ESTBODY DRN	5K01728	768455OST0038FL	00768455221363
423654	ESTBODY DRN	5K05130	768455OST0038FL	00768455221370
423657	ESTBODY DRN	5J03908	768455OST0038FL	00768455221400
423661	ESTBODY DRN	5K05141	768455OST0038FL	00768455221448

Refer to Appendix 2 for the country-specific list of impacted product codes and associated lot numbers

Distribution

Our records indicate that you may have received the affected units distributed on 10-2025.

User risk assessment

Convatec has completed an internal health hazard evaluation, which determined that the identified manufacturing variation may result in minor skin irritation in a limited number of users. The potential severity is considered low, and no adverse events have been reported to date.

Action to be taken by Distributor

- Review your inventory and identify whether you hold any of the affected product codes or lot numbers.
- Segregate and quarantine all affected stock immediately.
- Notify all downstream customers who may have received affected product. This letter may be used to support transmission of the communication.
- Complete the Response Form (**Appendix 1**) and return it to Convatec within 30 days.
 - **Acknowledgement of this action is critical for regulatory compliance.**
- If you confirm affected product on hand, Convatec will conduct a validation check.
- Once validated, formal authorisation from a Convatec representative will be issued to permit product destruction.
- Convatec will provide a Certificate of Destruction (COD) for completion.
- Destroy all affected product immediately upon receiving authorisation and return the signed COD to Convatec as evidence to support reconciliation.
- Your account will be credited for all destroyed product upon receipt of:
 - completed Response Form (**Appendix 1**), and
 - signed Certificate of Destruction (COD).
- Please ensure your account number is clearly indicated on Appendix 1.
- Our customer care teams are available to assist you with any questions and provide product alternatives if needed. Please contact your regional Convatec Customer Services european.customersupport@convatec.com

Action to be taken by End-user (*Healthcare Facilities / Direct Customers*)

- Review your personal supplies and determine if you are affected by this communication.
- We encourage you to dispose of affected units at your discretion however, disposal is optional as the risk associated with this issue is low.
- Complete Response Form - Appendix 1 and return to Convatec within 30 days.
 - **Acknowledgment of this action is critical. If you're not able to provide a written response liaise with your distributor or Convatec Customer Services can support.**
- Our customer care teams are available to assist you with any questions and provide product alternatives if needed. Please contact the regional Convatec Customer Services european.customersupport@convatec.com
- Report any complaints, product performance concerns, or adverse events through your usual reporting channels.

Action taken by Convatec

- Shipment of affected product has been stopped, and all remaining stock has been quarantined.
- Corrective and preventive measures are underway to prevent a reoccurrence.
- A voluntary Field Action across the impacted countries has been initiated.
- All relevant regulatory authorities have been notified in accordance with applicable requirements.

Transmission of this notice

- This notice needs to be disseminated on to all who need to be aware within your organization or to any organization 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.

Reporting to Authorities

The regulatory authority in your country has been informed of this communication as required. Please keep Convatec informed of any adverse events associated with this product through your usual reporting channels

Convatec remains committed to delivering high quality products and ensuring patient safety, and customer satisfaction. Thank you for your understanding and we apologize for any inconvenience this may have caused.

Yours faithfully,

Courtney Smith

Signed by:
Courtney Smith
 Signer Name: Courtney Smith
Signing Reason: I approve this document
Signing Time: Feb 13, 2026 | 3:34:07 PM GMT
18C584297FF34C80A5D3283D05D64343

Senior Director

Regulatory Affairs

APPENDIX 1

RESPONSE FORM

- Immediately complete
- If you have no affected product a completed response form is still required
- Please return the completed form via email

Issue Date: Feb-2026

CVT Recall Ref: TW-2555515

Original Notice: X

Revised Notice:

Revision Number: 1

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

Account No:		
Business Name:		
Address:		
<input type="checkbox"/>	I confirm receipt, understanding and acknowledgement of this notification	
<input type="checkbox"/>	I have checked my inventory, and I have product on hand	QTY
<input type="checkbox"/>	I have checked my inventory, quarantined, and disposed of affected inventory	
<input type="checkbox"/>	I have attached a Certificate of Destruction (COD) as requested evidence	
<input type="checkbox"/>	I have identified customers that received or may have received affected product	
<input type="checkbox"/>	I have informed the identified customers of this notification	Date Sent

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

APPENDIX 1



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ACTION ACKNOWLEDGEMENT

NAME	
POSITION	
SIGNATURE	
DATE (DD/MMM/YYYY)	

Appendix 2: Affected Product Per Region

Country	Product SAP Code	Product ICC Code	Lot Number	Date of Manufacture	Expiry Date	Classification
Denmark	1737652	423644	5J02728	12-Sep-25	01-Aug-28	Class I