3M Deutschland GmbH
Carl-Schurz-Straße 1
41453 Neuss

☎+49 (0)2131/140
🖷+49 (0)2131/142649
Internet: www.3M.de
E-Mail: innovation.de@3M.com
WEEE-Reg.-Nr. DE 36963167
VAT-ID: DE 120679179

<Customer address>

Field Safety Notice

Name of the affected product: 3M™ Coban™ Self-Adherent Wrap, (Latex Containing, Sterile)
Catalog Numbers 1584S, 1586S
FSCA-identifier: 2021-12 FSCA Coban
Type of action: Disposal of affected products

Date: December 20th, 2021

Attention: 3M Health Care Business Customers

Dear Customer,

3M is notifying all users in impacted European countries of the above-mentioned 3M™ Coban™ Self-Adherent Wrap, (Latex Containing, Sterile) of a field safety corrective action.

Description of the problem and potential hazard and risk for the patient/user:
This corrective action has been initiated due to the incorrect translation in the product description in the country car plates for Italy and Finland on the pouch label and corrugated shipper label. These product descriptions incorrectly add 'latex-free' into the descriptor, whereas this product is latex containing. The product is correctly marked with the Latex symbol. 3M is executing a corrective action for these product lots in order to minimize customer confusion regarding latex content and avoid potential risk associated with allergic reactions including anaphylaxis in latex sensitive individuals.

Sitz: 41453 Neuss · Handelsregister: B 1878 Amtsgericht Neuss
Geschäftsführer: Heinrich Brands, Dirk Lange, Oliver Leick
Vorsitzender der Geschäftsführung: Dirk Lange; Vorsitzender des Aufsichtsrates: Günter Gressler

Details on affected devices:
The following lots of Coban™ Self-Adherent Wrap, (Latex Containing, Sterile), catalog number 1584S and 1586S, are subject to this field safety corrective action:

Coban™ Self-Adherent Wrap, catalog number 1584S:

2024-01FN	2024-01HE	2024-02FZ	2024-04FH	33EWMW	33H5WH
2024-01FO	2024-02FB	2024-03HA	33E935	33FERN	
2024-01FU	2024-02FC	2024-03HH	33EHFT	33FJ6P	
2024-01FW	2024-02FD	2024-04FF	33ENYF	33H5FT	

Coban™ Self-Adherent Wrap, catalog number 1586S:

2024-02FA	2024-02FD	2024-02FK	33FA8T	33FDLR
2024-02FB	2024-02FJ	2024-02FL	33FDDE	33H6EX

Action to be taken by the user:
All users of the **3M™ Coban™ Self-Adherent Wrap, (Latex Containing, Sterile**) are being asked to take the following actions:

- Ensure all your internal and external customers are informed about this corrective action.
- Please inform us if you supplied the affected items to customers outside your home country.
- Please identify the affected product listed above, remove from your inventory, and do not use.
- Please discard all remaining affected product listed above per facility procedures.
- Complete and return by e-mail to meddev.de@mmm.com the enclosed Acknowledgement Form, indicating that the corrective action was understood and executed. Please also indicate the number of devices you have disposed of.

Transmission of this Field Safety Notice:
Please pass on this notice immediately to all departments who might use the concerned products. In addition, ensure that the information is provided to any organisation where the concerned products potentially have been distributed.

Thank you for your immediate attention and cooperation. We apologise for any inconvenience this matter may cause.

Contact reference person:

If you have questions, please contact your local 3M representative.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Dr. Marie Isabel Cobbers
Safety Officer
3M Deutschland GmbH, Health Care Business
Carl-Schurz-Strasse 1, 41453 Neuss, Germany
Mail: mcobbers@mmm.com

Acknowledgement Form – FSN 2021-12 FSCA Coban

Email completed form to: meddev.de@mmm.com

Please examine your inventory to determine if you have any stock of the affected product lots indicated below. Note, this notification only applies to the indicated lots of **3M™ Coban™ Self-Adherent Wrap, (Latex Containing, Sterile**)

☐ We have examined our inventory, identified the following quantity of units on hand and have disposed of them per facility protocol.

Catalog number	Number of rolls disposed
1584S	
1586S	

☐ We have examined our inventory and do not have any above listed lot of 3M™ Coban™ Self-Adherent Wrap, (Latex Containing, Sterile) on stock.

☐ I have communicated this information to all internal and external customers of my organisation.

☐ I acknowledge that I have read and understood this letter and will complete the actions requested.

Email completed form to: meddev.de@mmm.com

Person completing this form:

Name		Company /Hospital Name	
Signature		City, Country	
Date		Phone	
		E-mail	