

Urgent Field Safety Notice – Recall

Address of customer
& name of contact person

Sales Division

Lohmann & Rauscher GmbH & Co.KG
Westerwaldstr. 4 · D-56579 Rengsdorf
Tel.: XXXX/ Fax: XXXX
Email: xxxx.xxxx@de.LRmed.com

04.01.2024

Urgent Field Safety Notice (Product Recall)

Dear customers,

today, we have to inform you about a precautionary product recall:

Product(s) concerned	Suprasorb A+Ag Antimicrobial Calcium Alginate Wound Dressing, 10x10cm REF 20571
Batch(es) affected	212743311
L&R reference number	2024-01
Reason for FSN	Wrong expiry date on the primary packaging
Explanation	The printed expiry date on the primary packaging is showing 06/2026, which corresponds to a shelf life of 5 years. The correct expiry date of this batch is 06/2024, since the shelf life of this product is 3 years. The date was incorrectly printed on the primary packaging. The sterile single packaging and the secondary packaging (for transport) show the correct expiry date.
Expectable risk / harm	If the product is used after the expiry date, the performance of the product cannot be guaranteed any more.

The following measures arise for you from this:

- do not use the affected product(s) anymore
- return/destroy the products in stock
- inform all other affected persons (users, customers etc.)
- complete and return the confirmation form

We thank you in advance for your cooperation and apologize for any inconvenience.

With best regards,

Lohmann & Rauscher GmbH & Co KG

i.V. / on behalf of

XXXXYY
Sales department

i.V. / on behalf of

XXXXYY
Regional Vigilance Officer

Annex:

- 1) Confirmation form
- 2) Illustration of the affected product batch

Annex 1: Confirmation form

Urgent Field Safety Notice (Product Recall)

Product(s) concerned:	Suprasorb A+Ag Antimicrobial Calcium Alginate Wound Dressing 10x10cm REF 20571
Reason for FSN:	Wrong expiry date on the primary packaging

(please return via Fax to +49 2634 - 99 xxxx / via mail to xxxxx, until 29/02/2024)

* reimbursement is not possible for later responses

Sender:

Lohmann & Rauscher GmbH & Co. KG
Westerwaldstr.4
56579 Rengsdorf, Germany

Addressee:

Address of customer
+ name of contact person + customer number

& all users who use the mentioned products

Corrective Actions:

Please do not use the affected products anymore.

We request the following information and confirmation from you (as customer, distributor or retailer of the affected product batch(es)) for verification and for your reimbursement.

I hereby confirm that the affected products are no longer used. Moreover, all persons involved (including third parties, if provided with the affected products) have been informed about this urgent field safety notice.

Please select one:

- The affected products have been used up.
- The remaining products (including those provided to third parties) will be **returned** to L&R.
- The remaining products (including those provided to third parties) will be **destroyed**.

Date / Signature: _____

Printed Name: _____

Position: _____

Department / Institution: _____

Phone and Email: _____

Please enter the returned and destroyed products with quantities in the following table:

REF	Product	Batch(es)	Quantity returned products (Pcs.)	Quantity destroyed products (Pcs.)
20571	Suprasorb A+Ag Antimicrobial Calcium Alginate Wound Dressing, 10x10cm	212743311		

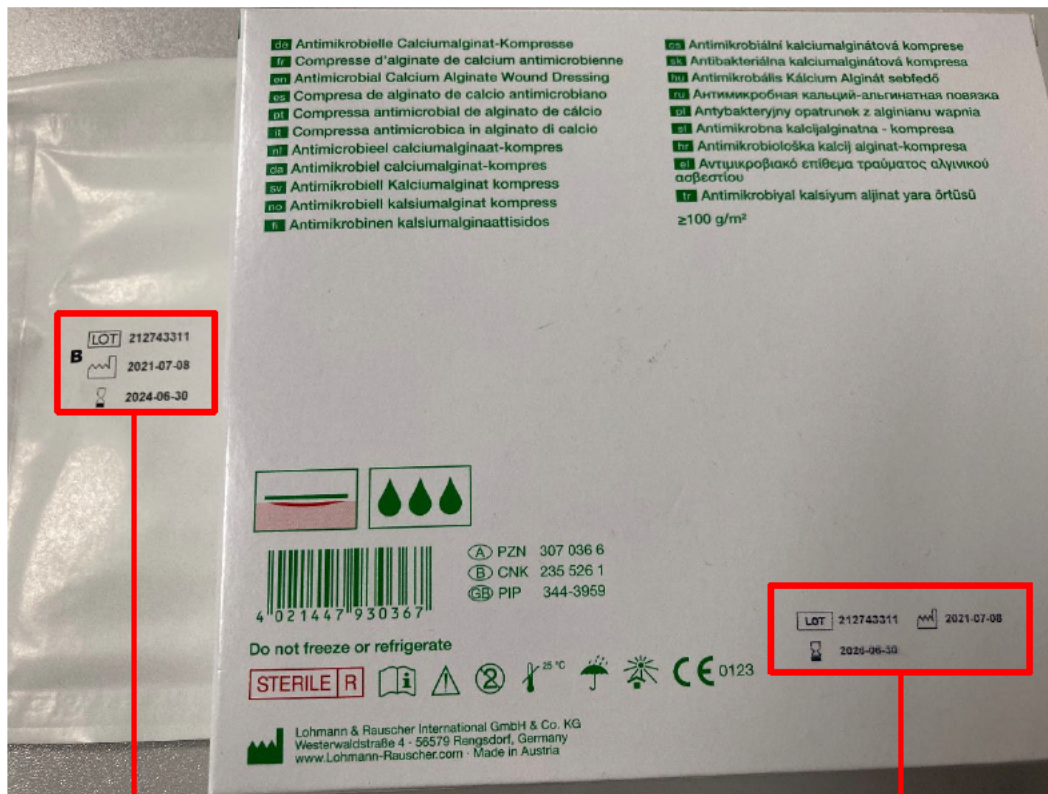
Please name a contact person in your company for returns processing*:

Name Function

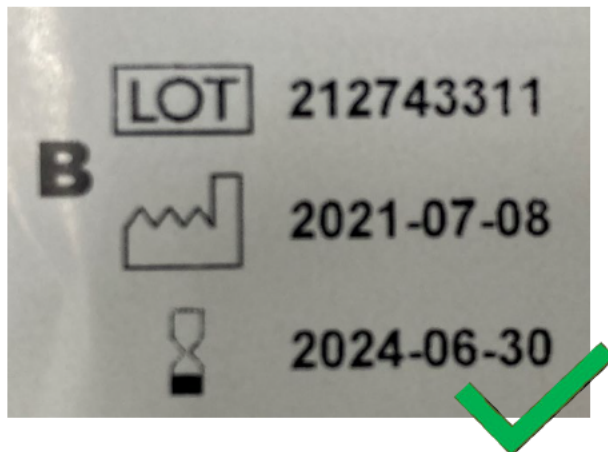
Telephone number Email

*Lohmann & Rauscher will get in touch with the named contact person for the purpose of handling returns!

Annex 2: Illustration of the affected product batch



Single sterile packaging



Primary packaging

