

Lohmann & Rauscher GmbH · Postfach/P.O. Box 222 · 1141 Wien/Vienna
Urgent Field Safety Notice – Recall

Insan Bakti SDN Bhd
Mrs. Vienna Mokhtar
2 Jalan SS19/1D
47500 Subang Jaya
Selangor

Malaysia

Sales APAC Export
Lohmann & Rauscher GmbH
Johann-Schorsch-Gasse 4
1140 Vienna
Tel.: 0043-1-57670-208/
Fax: 0043-1-57670-399
Email: mai.le@at.LRmed.com

Vienna 10.01.2024

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 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

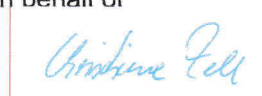
i.V. / on behalf of



Mai.Le@at.LRmed.com, Jan 10, 2024 02:39:45 PM UTC

Mai Le
Head of Export Southeast Asia
APAC Export

i.A. / on behalf of



Christiane.Zell@de.LRmed.com, Jan 10, 2024 02:36:09 PM UTC

Dr. Christiane Zell
Senior Regional Vigilance Officer APAC
Quality & Regulatory Affairs

Annex: 1) Confirmation form; 2) Illustration of the affected product batch

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 +43-1-57670-399 / via mail to mai.le@at.LRmed.com, until **29/02/2024)**

* reimbursement is not possible for later responses

Sender:

Sales APAC Export
Mrs. Mai Le
Lohmann & Rauscher GmbH
Johann-Schorsch-Gasse 4
1140 Vienna

Addressee:

Insan Bakti SDN Bhd
Mrs. Vianna Mokhtar
2 Jalan SS19/1D
47500 Subang Jaya
Selangor
Malaysia
& 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		

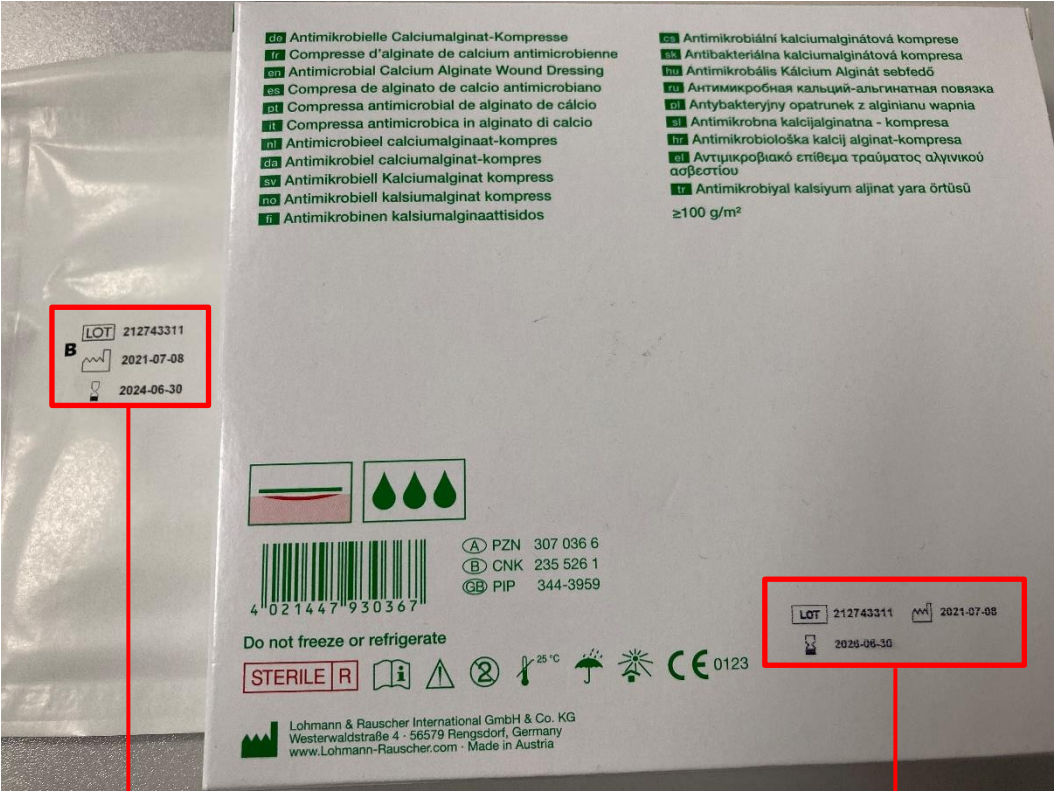
Please name a contact person in your company for returns processing*:

Name Function

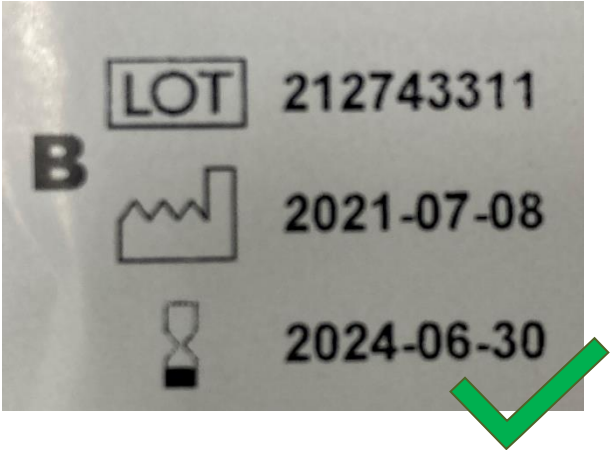
Telephone number Email

*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

