

Urgent Field Safety Notice – Recall

Nujno varnostno obvestilo stranki - odpoklic

Sales Division

Lohmann & Rauscher GmbH & Co.KG

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Email: Hannes.Schober@at.LRmed.com

Customer/*stranka*:

Sanolabor d.d.

Leskoškova cesta 4

SI-1000 Ljubljana

Date: 11.01.2024

Urgent Field Safety Notice (Product Recall)

Nujno varnostno obvestilo (odpoklic izdelka)

Dear customers,

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

danes vas moramo obvestiti o previdnostnem odpoklicu izdelkov:

Product(s) concerned <i>Prizadeti izdelek</i>	Suprasorb A+Ag Antimicrobial Calcium Alginate Wound Dressing, 10x10cm REF 20571
Batch(es) affected <i>Prizadeta serija</i>	212743311
L&R reference number	2024-01
Reason for FSN <i>Razlog odpoklica</i>	Wrong expiry date on the primary packaging <i>Napačen rok uporabnosti na primarni ovojnini</i>
Explanation <i>Obrazložitev</i>	The printed expiry date on the primary packaging is showing 06/2026, which corresponds to a shelf life of 5 years. <i>Natisnjen rok uporabnosti na primarni ovojnini prikazuje 06/2026, kar ustreza roku uporabnosti 5 let.</i> The correct expiry date of this batch is 06/2024, since the shelf life of this product is 3 years. <i>Pravilen rok uporabe te serije je 06/2024, saj je rok uporabnosti tega izdelka 3 leta.</i> The date was incorrectly printed on the primary packaging. The sterile single packaging and the secondary packaging (for transport) show the correct expiry date. <i>Na primarni embalaži je bil natisnjen napačen datum. Na sterilnem posameznem pakiranju in sekundarnem pakiranju (za transport) je naveden pravilen rok uporabnosti.</i>
Expectable risk / harm <i>Pričakovano tveganje/škoda</i>	If the product is used after the expiry date, the performance of the product cannot be guaranteed any more. <i>Če izdelek uporabljate po izteku roka uporabnosti, ni več mogoče zagotoviti učinkovitosti izdelka.</i>

The following measures arise for you from this: / Iz tega izhajajo vaši naslednji ukrepi:

- do not use the affected product(s) anymore / *prizadetih izdelkov ne uporabljajte več*
- return/destroy the products in stock / *vrnite/uničite izdelke na zalogi*
- inform all other affected persons (users, customers etc.) / *obvestite vse druge prizadete*
- complete and return the confirmation form / *izpolnite in vrnite potrditveni obrazec*

We thank you in advance for your cooperation and apologize for any inconvenience.
Že vnaprej se vam zahvaljujemo za sodelovanje in se opravičujemo za morebitne nevšečnosti.

With best regards,

Lohmann & Rauscher GmbH & Co KG

i.V. / on behalf of

i.V. / on behalf of

Daniel Dugi
Podružnica LR-SLO

Hannes Schober
Regional Vigilance Officer LRA

Annex:

- 1) Confirmation form / *potrditveni obrazec*
- 2) Illustration of the affected product batch / *ilustracija zadevne serije izdelka*

Annex 1: Confirmation form

Urgent Field Safety Notice (Product Recall)

Nujno varnostno obvestilo stranki (odpoklic izdelka)

Product(s) concerned: <i>Prizadeti izdelek:</i>	Suprasorb A+Ag Antimicrobial Calcium Alginate Wound Dressing 10x10cm REF 20571
Reason for FSN: <i>Razlog odpoklica:</i>	Wrong expiry date on the primary packaging <i>Napačen rok uporabnosti na primarni ovojnini</i>

(please return via Fax to +43 316 67300025 / via e-mail

to: daniel.dugi@si.LRMed.com, until 12/01/2024)* reimbursement is not possible for later responses

Sender / pošiljatelj:

Lohmann & Rauscher GmbH & Co. KG
Westerwaldstr.4, D-56579 Rengsdorf
Lohmann & Rauscher Podružnica SLO

Addressee / naslovník:

SANOLABOR d.d
Leskoškova cesta 4, SI-1000 Ljubljana
Albina Zalar, Head of regulation & quality management

& all users who use the mentioned products
in vsem uporabnikom, ki uporabljajo omenjene izdelke

Corrective Actions:

Korektivni ukrepi:

Please do not use the affected products anymore.

Prizadetih izdelkov ne uporabljajte več

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.

Od vas (kot stranke, distributerja ali prodajalca zadevnih serij izdelkov) zahtevamo naslednje podatke in potrditev za preverjanje in vaše povračilo

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.

S tem potrjujemo, da se prizadeti izdelki ne uporabljajo več. Poleg tega so bile vse vpletene osebe (vključno s tretjimi osebami, če so te prejele prizadete izdelke) obveščene o tem nujnem varnostnem obvestilu.

Please select one / prosimo izberite in označite:

- The affected products have been **used up** / *prizadeti izdelki so bili porabljeni.*
- The remaining products (including those provided to third parties) will be **returned** to L&R / *preostali izdelki (vključno tisti poslani tretjim osebam) bodo vrnjeni v L&R.*
- The remaining products (including those provided to third parties) will be **destroyed** / *preostali izdelki (vključno tisti poslani tretjim osebam) bodo uničeni.*

Please enter the returned and destroyed products with quantities in the following table:
Vrnjene in uničene izdelke s količinami vnesite v naslednjo tabelo:

REF	Product	Batch	Quantity returned products (Pcs.) <i>vrnjeno</i>	Quantity destroyed products (Pcs.) <i>uničeno</i>
20571	Suprasorb A+Ag Antimicrobial Calcium Alginate Wound Dressing, 10x10cm	212743311 (200 pcs)		

Please name a contact person in your company for returns processing*:
*Navedite kontaktno osebo v vašem podjetju za obdelavo vračil**

Albina Zalar, Head of regulation and quality management

Name _____ Function _____

+385 1 5854310 albina.zalar@sanolabor.si

Telephone number _____ Email _____

*Lohmann & Rauscher will get in touch with the named contact person for the purpose of handling returns!
**Lohmann & Rauscher bo stopil v stik z imenovano kontaktno osebo za namen vračila izdelkov!*

Date / Signature: 11.01.2024, podpis: _____

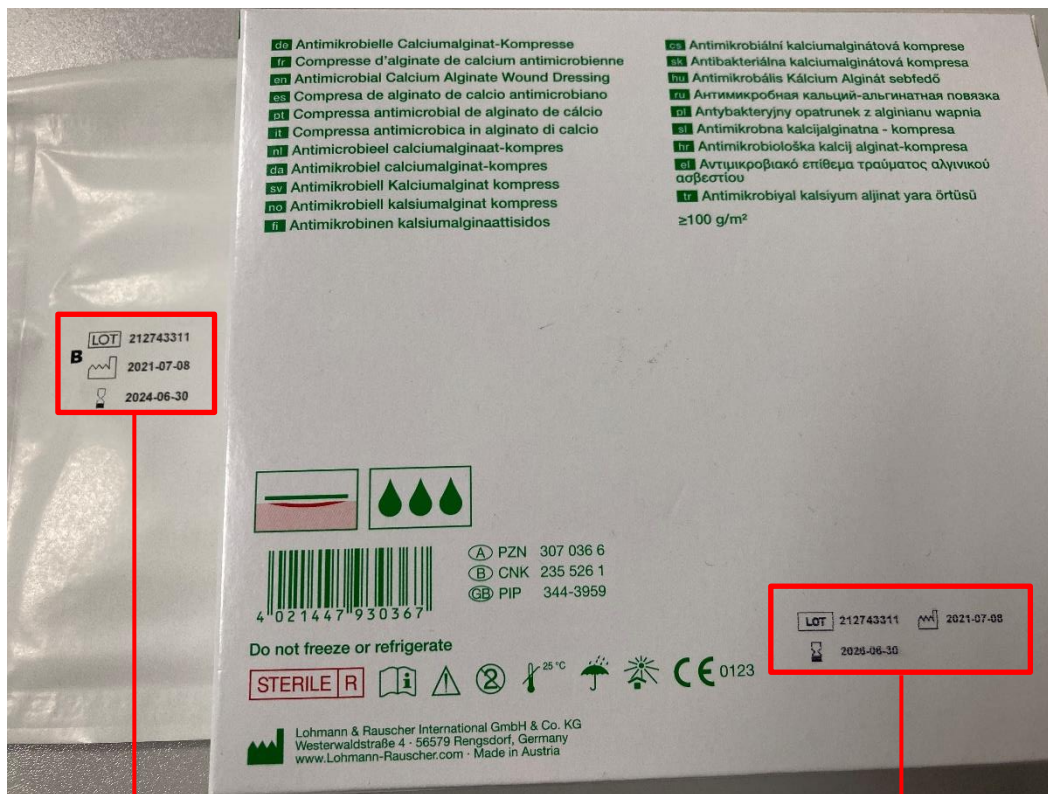
Printed Name: Albina Zalar

Position: Head of regulation and quality management, Sanolabor

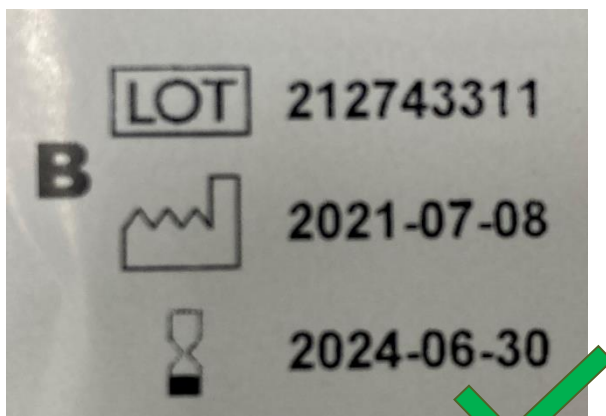
Department / Institution: Sanolabor d.d. Ljubljana

Phone and Email: +385 1 5854310 albina.zalar@sanolabor.si

Annex 2: Illustration of the affected product batch



Single sterile packaging



Primary packaging

