

Urgent Field Safety Notice

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

15.05.2024

Urgent Field Safety Notice

Dear customers,

today, we have to inform you about the following facts:

Product(s) concerned	Suprasorb CNP endo Kit Oral REF 34199
Batch affected	23028199
L&R reference number	2024-06
Reason for FSN	Shortening shelf life and changing the batch number
Explanation	Due to the results of internal stability tests, the shelf life has been shortened (from 28 months to 18 months). Therefore the product with the batch 234028199 will be relabelled with a shortened shelf life and changed batch number.
Expectable risk / harm	If the product is used after the shelf life, the performance of the product cannot be guaranteed any more.

The following measures arise for you from this:

- The products you have in stock will be relabelled by our sales force representative
- Inform all other affected persons (users, customers etc.)
- Fill out the confirmation form and return it to us

We thank you in advance for your co-operation and ask for your understanding.

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

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Product(s) concerned:	Suprasorb CNP endo Kit Oral REF 34199
Reason for FSN:	Shortening shelf life and changing the batch number

(please return by Fax to **+49 2634 - 99 xxxx** / by mail to **xxxxx**, until **09 June 2024**)

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: Information (shortening the shelf life, changing the batch number)

For confirmation, please provide the following information or acknowledgement as a customer, dealer or retailer of the affected product batch.

I hereby confirm that the affected products can be relabelled by the L&R sales force representative (shortening the shelf life, changing the batch number). In addition, all persons involved (including third parties, if they have been supplied with the affected products) have been informed of this urgent field safety notice.

Date / Signature: _____

Printed Name: _____

Position: _____

Department / Institution: _____

Phone and Email: _____