

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

14.02.2024

Urgent Field Safety Notice (Product Recall)

Dear customers,

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

Product(s) concerned	Setpack® Individual Sterile surgical jersey (made from cotton) [14 REF numbers] Kitpacks containing the jersey component [39 REF numbers]
Batch(es) affected	674 batches
L&R reference number	2024-03
Reason for FSN	Sterility of the products cannot be guaranteed
Explanation	During a microbiological resistance check, it was found that the Setpack Jerseys made from raw cotton did not pass the sterility tests. This is most likely due to spores that were not sufficiently killed by the sterilization process. Therefore, sterility cannot be guaranteed.
Expectable risk / harm	As the Setpack Jersey products are used in the operating theatre, this potential unsterility could lead to wound infections.

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

Urgent Field Safety Notice (Product Recall)

Product(s) concerned:	Setpack® Individual Sterile surgical jersey (made from cotton) [14 REF numbers]
	Kitpacks containing the jersey component [39 REF numbers]
Reason for FSN:	Sterility of the products cannot be guaranteed

(please return via Fax to **+49 2634 - 99 xxxx** / via mail to **xxxxx**, until **31/03/2024**)

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:

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	Setpack® Individual Sterile surgical jersey	xxxx		
13624	Setpack® Individual Sterile surgical jersey	xxxx		
82713	Setpack® Individual Sterile surgical jersey	xxxx		
82758	Setpack® Individual Sterile surgical jersey	xxxx		
xxx	Kitpacks containing the jersey component	xxx		

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!