

# Field Safety Notice – Recall

Lohmann & Rauscher BV  
Antennestraat 86 B . 1322 AS ALMERE  
Tel.: 036 – 54 63 020  
Email: info@NL.LRmed.com

28 augustus 2017

## Urgent Field Safety Notice Product Recall due to possible unsterility

| REF   | Product                     | Lot        |
|-------|-----------------------------|------------|
| 23094 | Metalline Tracheo 8x9 50ste | 1728112208 |

Dear Sir or Madam,

Today, in terms of patient safety, we would like to inform you about the precautionary product recall of the above mentioned product.

### Event

**In the course of a control of the production process by our Quality Assurance Department (QA), in single cases leakages (cannulas) were discovered in the sealing of the sterile packaging of the final products (14 products with leakages (cannulas) in 82.200 products tested). The affected batch was partly delivered in the market (in the market: 36.950 pieces).**

### Further procedure

The probably affected products were immediately separated and the affected batch was blocked in the warehouse.

Until today we have not received any complaints from the market. Theoretically, the unsterility could cause inflammation or infection on the tracheostoma.

Please send the affected batches of the products (see list in enclosure) with the enclosed form back to us (small amounts can be destroyed locally). You will receive a credit note for the returned/destroyed products in short term.

Please ensure within your organization that all users of the above mentioned products and other relevant persons are aware of this **Urgent Field Safety Notice** and send the enclosed confirmation back to us.

If you have delivered the product to third parties, please forward a copy of that information to them.

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

Yours truly,

Lohmann & Rauscher BV

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Sales & Marketing Director

### Attachment:

Urgent Field Safety Notice, Product Recall due to possible unsterility.  
List of affected articles and batches

**Urgent Field Safety Notice!**

**28 augustus 2017**

**Product Recall due to possible unsterility**

**Sender:** Lohmann & Rauscher BV  
Antennestraat 86 B . 1322 AS ALMERE

**Addressee:** Adresse  
Xxx  
xxx  
& all users who use the below mentioned products.

**Description:** Recall of the following products due to possible unsterility

| REF   | Product                     | Lot        |
|-------|-----------------------------|------------|
| 23094 | Metalline Tracheo 8x9 50ste | 1728112208 |

**Corrective Actions:**

We ask you not to use the above mentioned product anymore and to send them back to us!

To ensure a free return to us, please contact our L&R returns department:

**Mrs. Liesbeth de Leeuw, Manager Logistics, 036 – 54 63 020, [info@NL.LRMed.com](mailto:info@NL.LRMed.com)**

Contact Person for Lohmann & Rauscher within your facility:

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Name \_\_\_\_\_ Function \_\_\_\_\_

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Telephone number \_\_\_\_\_ Email \_\_\_\_\_

Please inform your employees who use the product of this Field Safety Notice and confirm to us that the product is not used anymore and the product has been returned to us or have been destroyed locally.

The undersigned confirms (please tick):

- that he does not possess the above mentioned product anymore,
- that he has not given the above mentioned product to third parties,
- that if he has given the above mentioned product to employees or third parties, he has informed the employees and third parties about the recall,
- that he will return the above mentioned product, which have been delivered to him and are still in his possession or in the possession of third parties, to Lohmann & Rauscher, Antwoordnummer 1012, 1300 VG ALMERE
- that he destroyed a small amount locally (maximum: 2 packages = 100 pieces).

Please enter the returned products with quantity in the following table and **enclose a copy of this sheet with the returned products:**

| REF   | Product                     | Lot        | Quantity of returned products | Destroyed |
|-------|-----------------------------|------------|-------------------------------|-----------|
| 23094 | Metalline Tracheo 8x9 50ste | 1728112208 |                               |           |

Date / Signature : \_\_\_\_\_

Printed Name: \_\_\_\_\_

Position: \_\_\_\_\_

Department / Institution: \_\_\_\_\_

Phone and Email: \_\_\_\_\_