

Lohmann & Rauscher GmbH · Postfach 222 · 1141 Wien

Field Safety Notice - Recall

Dr. [REDACTED]
 [REDACTED]
 [REDACTED]

Date 13 June 2016

Handelsgericht:
 Wr. Neustadt
 FN 111 925 x
 ILN/GLN 402 144 756 000 7
 UID: ATU 150 137 04
 EORI-Nr: ATEOS1000001232
 ARA-Lizenznr: 80535

Bankkonto:
 UniCredit Bank Austria AG
 IBAN:
 AT09 1100 0004 8672 5500
 BIC/SWIFT: BKAUATWW

Urgent Field Safety Notice
Product Recall due to possible contamination with metal needles in
Metalline products

| REF | Product | Lot |
|-------|--|-----------|
| 23080 | Metalline Wound dressing 5/10 1Stk gero | 605212315 |
| 23082 | Metalline wound dressing 10x12 50ste | 550512208 |
| 23084 | Metalline wound dressing 10x12 10ste | 550512208 |
| 23088 | Metalline Drain-K Kruetten 6x7 8000Stk | 551412208 |
| 23093 | Metalline Drain 6x7 50ste | 603212208 |
| 23093 | Metalline Drain 6x7 50ste | 606412208 |
| 23093 | Metalline Drain 6x7 50ste | 609212208 |
| 23093 | Metalline Drain 6x7 50ste | 614312208 |
| 23094 | Metalline Tracheo 8x9 50ste | 606512208 |
| 23094 | Metalline Tracheo 8x9 50ste | 609412208 |
| 23094 | Metalline Tracheo 8x9 50ste | 614512208 |

Dear Sir or Madam,

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

During the quality control process parts of needles or whole needles were detected on or in the backfacing nonwoven of some final products. The needles are from the needling process during manufacturing of the backfacing nonwoven, which are usually detected by a metal detector and separated.



The probably affected products were immediately separated and the affected batches were blocked in the warehouse. Until today we have not received any complaints from the market.



However, as we can not completely exclude that products with metal needles have already been delivered to customers, we decided to perform a precautionary recall of the products in terms of patient safety.

Please send the affected batches of the products (see list in enclosure) with the enclosed form back to us .You will receive a credit note for the returned 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 GmbH & Co KG
i.V. / On behalf of


Mag. Krisztina Bojtor-Mörwald, MBA
Head of Export Europe

i.V. / On behalf of


Mag. Rudolf Duris
Regional Vigilance Officer

Attachment:

Urgent Field Safety Notice, Product Recall due to possible contamination with metal needles in Metalline products
List of affected articles and batches



Urgent Field Safety Notice!

June 13th, 2016

Product Recall due to possible contamination with metal needles in Metalline products

Via E-Mail: susanne.nussbaumer@at.lrmed.com

Sender: Lohmann & Rauscher GmbH
Johann-Schorsch-Gasse 4
1141 Wien

Addressee: [Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]

& all users who use the below mentioned products.

Description: Recall of the following products due to possible contamination with metal needles in Metalline products

- **Metalline products affected**
Article numbers and batches see enclosure

Corrective Actions:

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

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

Mr. Boris Dosen **Tel. +43/1/57670/308**
E-Mail: boris.dosen@AT.LRMed.com

Contact Person for Lohmann & Rauscher within your facility:

| Name | Function |
|------|----------|
| | |

| Telephone number | Email |
|------------------|-------|
| | |

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

The undersigned confirms (please tick):

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

The batches and amounts are listed in the table below.



Please enter the returned products with quantity in the following table:

| REF | Product | Lot | Quantity of returned products | De-destroyed |
|-------|---------------------------------|-----------|-------------------------------|--------------|
| 23093 | Metalline Drain-Kompr 6x7 50ste | 603212208 | | |

Date / Signature :

Printed Name:

Position:

Department / Institution:

Phone and Email:



Confirmation:

**(via Fax to +43/1/5771799 Susanne Nußbaumer
Via E-Mail: susanne.nussbaumer@at.lrmed.com)**

We informed our national authority about

**Product Recall due to
possible contamination with metal needles in Metalline products**

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Date / Signature :

Printed Name:

Position:

Department / Institution:

Phone and Email:
