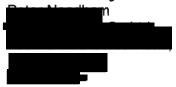


Lohmann & Rauscher GmbH - Postfach 222 · 1141 Wien

Field Safety Notice - Recall



Date 13 June 2016

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 <u>a precautionary product</u> <u>recall</u> 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.

Lohmann & Rauscher GmbH

Johann-Schorsch-Gasse 4 Postfach 222 · 1141 Wien

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info@at.LRmed.com www.lohmann-rauscher.at

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



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

Mag. Rudof Duris

On behalf

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:



& all users who use the below mentioned products.

<u>Description:</u> 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 <u>not to use</u> 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	
Talanhana awaka	F II	
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,
I that he has not sives the characteristics of sundivide to third section

- [] 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 in formed 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- stroyed
23093	Metalline Drain-Kompr 6x7 50ste	603212208		

Date / Signature :	
Printed Name:	
Position:	
Department / Institution:	
Phone and Email:	<u> </u>



Confirmation:

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

We informed our national authority about

<u>Product Recall due to</u> <u>possible contamination with metal needles in Metalline products</u>

REF	Product	Lot
23080	Metalline Wound dressing 5/10 1Stk gero	605212315
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23094	Metalline Tracheo 8x9 50ste	609412208
23094	Metalline Tracheo 8x9 50ste	614512208

Date / Signature :		
Printed Name:		
Position:	-	
Department / Institution:	·	
Phone and Email:	-	