



Lohmann & Rauscher GmbH · Postfach/P.O. Box 222 · 1141 Wien/Vienna

## Urgent Field Safety Notice – Recall

Ireland

September 10, 2019

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

REF	Product
36015	Meche de Gaze, sterile, 10 cm x 5 m

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.

#### **In a newly performed sterility test, it was found that partial unsterility may be present**

The affected products and batches were immediately quarantined in the warehouse.

Theoretically, the unsterility could lead to inflammation or infection.

Please return the products in the attachment with the enclosed form. Small quantities (1 pack, 1 shelf container (SC)) can be destroyed (with confirmation of destruction). Of course, the products will be exchanged free of charge or credited upon request.

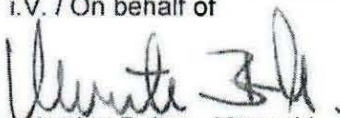
Please ensure within your organization that all users of the above mentioned products and other relevant persons are aware of this **Urgent Field Safety Notice** and send the enclosed confirmation back to us.

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

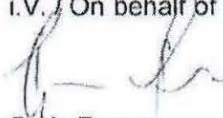
We thank you in advance for your cooperation and apologize for any inconvenience.

Yours truly,

Lohmann & Rauscher GmbH  
i.V. / On behalf of

  
 Krisztina Bojtor - Mörwald  
 Head of Export Europe

i.V. / On behalf of

  
 Boris Dosen  
 Country Manager

#### Attachment:

- 1) Urgent Field Safety Notice, Product Recall due possible unsterility



**Enclosure 1**

**Urgent Field Safety Notice!**

**September 10, 2019**

**Product Recall due to possible unsterility**

**via E-Mail: Boris.Dosen@at.LRmed.com**

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

**Addressee:** Nimex Trading Co. LTD  
290 Harold's Cross Road  
6, Dublin  
Ireland

& all users who use the below mentioned products.

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

REF	Product
36015	Meche de Gaze, sterile, 10 cm x 5 m

**Corrective Actions:**

Please do not use the Meche de Gaze anymore.

Please inform all employees who use the products about this safety message and confirm that you are not using the Meche de Gaze.

The undersigned confirms (please tick):

- [...] that he does not use the Meche de Gaze,
- [...] that he informs all persons involved about this important information about the above mentioned products,
- [...] that he no longer owns the products listed above,
- [...] that he has not given the above mentioned products to third parties,
- [...] that he has informed third parties, if they have received from him the above-mentioned products, about the safety information and non-use of the Meche de Gaze products.
- [...] that the affected products delivered to him that are still in his or her possession or in the possession of a third party, will be returned to Lohmann & Rauscher GmbH
- [...] that small amounts of the products are destroyed directly on site (1 pack = 1 shelf container (SC)) can be destroyed (with confirmation of destruction). Please note the lot number (batch) and quantity in the table below.

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

**Ms. Carina Feyrer**

**Tel.: +43/1/57670-308**

**E-Mail: Carina.Feyrer@at.LRmed.com**