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Chamber of commerce 23038479
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Contact
Medeco Customer Service

Email
info-medecobv@mediq.com

Date
2 October 2023

Our reference
FSN2023-1

Subject
URGENT- Field Safety Notice – End User
Klinion Kliniray Gauze Compress X-Ray
Klinion Kliniray Abdominal Gauze Compress X-Ray

Dear Sir/Madam,

Medeco BV initiated a product recall for specific product codes and lot numbers of the Klinion Kliniray Gauze Compress X-Ray and Klinion Kliniray Abdominal Gauze Compress X-Ray. Please note that it does not affect all product codes of the Klinion Kliniray Gauze Compress X-Ray and Klinion Kliniray Abdominal Gauze Compress X-Ray.

Description of the problem:

After assessment of these products, it became known that x-ray threads in gauze compresses can disintegrate. It has been confirmed that these products are not meeting the required criteria.

Theoretically, small pieces of thread could be left behind if the x-ray thread breaks or frays. This may, for example, lead to inflammation and/or granuloma formation when remaining in the body.

The identified product codes and lot numbers within this notice are potentially affected. For this reason and to address any potential risk of harm, all of the affected products should not be used.

Product identification procedure:

The only way to identify affected products is by checking product code and lot number to the recalled product list (see attachment 1).
Attachment 2 gives an example of a packaging label that highlights the location of the product code and lot number on the device labels. The label can be found on the primary packaging and the carton. The product code (reference number) is preceded by the word REF. The lot number is preceded by  and is in 4500xxxxxx format.

Advice on actions to be taken by End User

Our records show that you have taken delivery of affected product. Please follow the steps below:

1. Please stop the use of all affected devices as defined in this document.
2. Check stock and ensure that all affected devices that you have in stock are quarantined.
3. Complete the enclosed 'Recall Response Form for END USERS' which should be forwarded to us as soon as possible.
   Contact your distributor to arrange return of affected products, if applicable, and to arrange credit.

Please provide a completed response as soon as possible.

Transmission of this Field Safety Notice

This notice should be sent to anyone who has received the affected devices within your organisation and to any organisation where the affected devices have been transferred to.

We are committed to deliver products of high quality to our customers and we apologize for any inconvenience that this notice can cause.
If you have any questions relating to this recall, please contact us at number provided above.

The relevant National Authorities have been informed about this Field Safety Corrective Action.

Authorisation:

Name:	Maria Silabon
Function:	Head of MOB enabling functions
Date: Signature:	2.10.2023

RECALL RESPONSE FORM for END USER

URGENT – FIELD SAFETY NOTICE

Please complete and return by email to *Please provide Mediq contact details*

Consignee:

Consignee Name:	
Consignee Address:	

Deliveries to your facility:

Invoice #	Product Code (REF number)	SAP no.	LOT no.	Quantity delivered (pieces)

Please answer each of the following questions:

1. Do you have any affected product Yes / NO

If yes: We have the following affected product:

Record quantity (pieces) for each LOT to be disposed:

Product Code (REF number)	SAP no.	LOT no.	Quantity (pieces)

Please provide details of affected products that were distributed to your customers:

Customer / Company name	Product Code (REF number)	SAP no.	LOT no.	Quantity (pieces)

END USER FORM Completed and returned from:

Name:	
Function:	
Company name:	
Address:	
Email address:	
Phone number:	
Signature:	
Date:	

Appendix 1
Products including lot numbers affected:

Medeco Article Number	Product REF number	LOT number	Name and description
3016720	111180	4500131696	KLINION GAASK 10X10 12L XRAY 50ST
3016720	111180	4500142292	KLINION GAASK 10X10 12L XRAY 50ST
3016720	111180	4500142298	KLINION GAASK 10X10 12L XRAY 50ST
3016720	111180	4500159100	KLINION GAASK 10X10 12L XRAY 50ST
3016722	111209	4500131696	KLINION GAASK 10X20 12L XRAY 50ST
3016722	111209	4500134619	KLINION GAASK 10X20 12L XRAY 50ST
3016722	111209	4500139418	KLINION GAASK 10X20 12L XRAY 50ST
3016722	111209	4500142298	KLINION GAASK 10X20 12L XRAY 50ST
3016722	111209	4500150886	KLINION GAASK 10X20 12L XRAY 50ST
3016722	111209	4500154489	KLINION GAASK 10X20 12L XRAY 50ST
3016722	111209	4500159105	KLINION GAASK 10X20 12L XRAY 50ST
3016736	115001	4500142292A	KLINION GAASK 5X 5 12L XRAY *S* PIP10
3016736	115001	4500142292B	KLINION GAASK 5X 5 12L XRAY *S* PIP10
3016737	115005	4500131696	KLINION GAASK 10X10 12L XRAY *S* PIP5
3016737	115005	4500136318	KLINION GAASK 10X10 12L XRAY *S* PIP5
3016737	115005	4500139418	KLINION GAASK 10X10 12L XRAY *S* PIP5
3016737	115005	4500142292A	KLINION GAASK 10X10 12L XRAY *S* PIP5
3016737	115005	4500142292B	KLINION GAASK 10X10 12L XRAY *S* PIP5
3016739	115007	4500131696	KLINION GAASK 10X10 12L XRAY *S* PIP10
3016739	115007	4500134619	KLINION GAASK 10X10 12L XRAY *S* PIP10
3016739	115007	4500139418A	KLINION GAASK 10X10 12L XRAY *S* PIP10
3016739	115007	4500139418B	KLINION GAASK 10X10 12L XRAY *S* PIP10
3016739	115007	4500142301	KLINION GAASK 10X10 12L XRAY *S* PIP10
3016739	115007	4500142293	KLINION GAASK 10X10 12L XRAY *S* PIP10
3016739	115007	4500142299	KLINION GAASK 10X10 12L XRAY *S* PIP10
3016739	115007	4500150886	KLINION GAASK 10X10 12L XRAY *S* PIP10
3016739	115007	4500159105	KLINION GAASK 10X10 12L XRAY *S* PIP10
3016739	115007	4500163488	KLINION GAASK 10X10 12L XRAY *S* PIP10
3016740	115020	4500131696	KLINION GAASK 10X20 12L XRAY *S* PIP5
3016740	115020	4500148507B	KLINION GAASK 10X20 12L XRAY *S* PIP5
3016740	115020	4500154489	KLINION GAASK 10X20 12L XRAY *S* PIP5
3016741	115021	4500123945	KLINION GAASK 10X20 12L XRAY *S* PIP10
3016741	115021	4500131696	KLINION GAASK 10X20 12L XRAY *S* PIP10
3016741	115021	4500134619A	KLINION GAASK 10X20 12L XRAY *S* PIP10
3016741	115021	4500134619B	KLINION GAASK 10X20 12L XRAY *S* PIP10
3016741	115021	4500139418	KLINION GAASK 10X20 12L XRAY *S* PIP10
3016741	115021	4500142293	KLINION GAASK 10X20 12L XRAY *S* PIP10
3016741	115021	4500142298	KLINION GAASK 10X20 12L XRAY *S* PIP10
3016741	115021	4500148507	KLINION GAASK 10X20 12L XRAY *S* PIP10
3016741	115021	4500150886	KLINION GAASK 10X20 12L XRAY *S* PIP10
3016741	115021	4500154490	KLINION GAASK 10X20 12L XRAY *S* PIP10
3016741	115021	4500157250	KLINION GAASK 10X20 12L XRAY *S* PIP10
3016741	115021	4500159102	KLINION GAASK 10X20 12L XRAY *S* PIP10
3016741	115021	4500159105	KLINION GAASK 10X20 12L XRAY *S* PIP10

Medeco Article Number	Product REF number	LOT number	Name and description
3016742	115023	4500139418A	KLINION GAASK 10X20 24L XRAY *S* PIP5
3016742	115023	4500139418B	KLINION GAASK 10X20 24L XRAY *S* PIP5
3016742	115023	4500142299	KLINION GAASK 10X20 24L XRAY *S* PIP5
3016742	115023	4500150887	KLINION GAASK 10X20 24L XRAY *S* PIP5
3016742	115023	4500157250	KLINION GAASK 10X20 24L XRAY *S* PIP5
3016744	115046	4500134619	KLINION GAASK 20X25 16L XRAY *S* PIP5
3016744	115046	4500142299	KLINION GAASK 20X25 16L XRAY *S* PIP5
3016746	115048	4500163297	KLINION GAASK 20X25 32L XRAY *S* PIP2
3016749	115062	4500139419A	KLINION BUIKGAAS 45X45 4L XRAY *S*

Appendix 2
Example of packaging labelling

Primary packaging

Outer carton label