



Medline International Germany GmbH  
Medline-Straße 1-3  
D-47533 Kleve  
Tel: +49 (0) 2821 – 7510 – 0  
Fax: +49 (0) 2821 – 7510 – 7802

Regulatory Affairs  
Quality Department  
gmb-eu-ra-kleve@medline.com  
Tel: +49 (0) 2821 – 7510 – 7528  
Fax: +49 (0) 2821 – 7510 – 7804

[www.medline.com/de](http://www.medline.com/de)

Customer No.:

Medline International Germany GmbH –Medline Str. 1-3 - D-47533 Kleve

Kleve, 14th August 2019

***URGENT: FIELD SAFETY NOTICE***  
***Medical Device Safety Advisory Notice***

For the attention of: the Pharmacist responsible for medical device vigilance and the Biomedical Engineering Department.

SECURITY INFORMATION of Medline Sterile Absorbent Cotton O.R Towels

Medline reference: FSN-19/03  
Description: Medline Sterile Absorbent Cotton O.R Towels.  
Product Codes concerned: See details in the table of the Acknowledgment receipt form below  
MoH reference:

Dear Customer,

This letter is to inform you of an urgent safety notification concerning Medline sterile absorbent OR Towels.  
Its objective is to draw users' attention on the recommendations of use.

Recommendations for Use:

Medline sterile cotton O.R towels are Class I Rule 4 non-invasive towels used to absorb fluids, including blood and body fluids at the surgical incision site or for drying hands.  
For fluids absorption inside the abdomen, a laparotomy sponge is an appropriate medical device as classified: IIa Rule 7 Surgically invasive short-term use.

There is no standard applicable to particulate release for woven absorbent towels.  
Recently, Medline has observed an increase of linting on these towels and if used in-correctly they can release cotton particles in the incision site.  
Medline is working closely with its supplier to reduce linting of the cotton towels.

Warning:

If you are using Medline OR towels as an invasive absorbent pad, then it is recommended to use a more appropriate device such as Lap Sponges.  
Please contact your sales representative for any further details.

Please return the acknowledgement form by fax or by email no later than August 30th, 2019

Yours Sincerely,

Quality and Regulatory Affairs Dept.



Medline International Germany GmbH  
Medline-Straße 1-3  
D-47533 Kleve  
Tel: +49 (0) 2821 – 7510 – 0  
Fax: +49 (0) 2821 – 7510 – 7802

Regulatory Affairs  
Quality Department  
gmb-eu-ra-kleve@medline.com  
Tel: +49 (0) 2821 – 7510 – 7528  
Fax: +49 (0) 2821 – 7510 – 7804

[www.medline.com/de](http://www.medline.com/de)

Acknowledgement receipt to fax to the following fax number: +49 2821 7510 7822  
or send by email to: [gmb-eu-ra-kleve@medline.com](mailto:gmb-eu-ra-kleve@medline.com)

Reference: FSN-19/03

Please complete this form and return to Medline by either fax or email as soon as possible, but no later than August 30th, 2019.

Table:

The references of Sterile OR Towels concerned by this notification are:

Reference	Description
28200004CEA	4 absorbent cotton O.R. 14077 towels, green, 66 cm x 43 cm
28700002CEA	2 absorbent cotton O.R. towels, blue, 66 cm x 43 cm
28700002XR	2 absorbent X Ray cotton O.R. towels, blue, 66 cm x 43 cm
28700004CEA	4 absorbent cotton O.R. towels, blue, 66 cm x 43 cm
28700004XR	4 absorbent cotton O.R. towels, blue, 66 cm x 43 cm X-ray detectable

I have read and understand the instructions provided by Medline. I acknowledge receipt of the FSN-19/03 regarding the Medline Sterile Absorbent Cotton O.R Towels by signing and returning this form.

I also agree to further distribute and communicate this important information within my facility as required. If you are a distributor, please inform your customers.

Date: \_\_\_\_\_

Customer Number: \_\_\_\_\_

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

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

Facility: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_

Telephone: \_\_\_\_\_

Fax: \_\_\_\_\_

Signature: \_\_\_\_\_