

PAUL HARTMANN AG
Paul-Hartmann-Strasse 12
89522 Heidenheim

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Germany

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Going further
for health

Urgent Field Safety Notice

Instructions to Affiliate

Field Safety Corrective Action: Voluntary Product Recall

Trade name: Tela® products, Longuetten and corresponding procedure trays (CombiSet®)

Article number and LOT: according to attachment 1

September 1st, 2020

Sender: PAUL HARTMANN AG
Paul-Hartmann-Str. 12
89522 Heidenheim
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Recipient: „affiliate / authorized distributor“

Affected product:

Affected Tela® products, Longuetten and corresponding procedure trays (CombiSet®) see attachment 1

Description of the problem and Product Advisory Notice:

The listed Tela® products are gauze products (compresses, swabs, lap sponges) containing an interwoven x-ray detectable thread. The listed procedure trays (CombiSet®) contain affected Longuetten.

Due to feedback from clinics and the information of the supplier of our x-ray products we learned that the x-ray thread of the affected Tela® products might break and lint upon mechanical stress.

The affected products and LOTs were immediately set under quarantine in our warehouses.

Breakage or linting of the x-ray thread might lead to small particles. Remaining of such particles in the body might lead to inflammation and development of granuloma.

For the PAUL HARTMANN AG safety of patients, users and third parties has the highest priority. Therefore, we voluntarily recall the products and batches listed in attachment 1.

IILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück
(Vorsitzende des Vorstands/CEO), François Georgelin,
Dr. Raymund Heinen, Michel Kuehn, Stefan Müller
Aufsichtsratsvorsitzender/Chairman of the Supervisory Board: Fritz-
Jürgen Heckmann

Sitz Heidenheim
Amtsgericht Ulm HRB 661090
Registered Office Heidenheim
Commercial Register of the District Court of Ulm file no. HRB 661090

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Corrective Action:

Please examine your inventory, block available stocks and do not use the affected products of the list any longer.

We kindly ask you to confirm the receipt of this notification and return attachment 2 (Response form 1 Affiliate Reception & Transmission) **until Tuesday, 08.09.2020**.

For confirmation of closure please complete and return attachment 3 (Response form 2 Affiliate Closure) **until Friday, 25.09.2020**.

Response form 1:

Affiliate Reception & Transmission to confirm having informed all respective people and organizations of this urgent field safety notification **until 08.09.2020**

Response form 2: Affiliate Closure after examination of your inventory and reception of the feedback from your customers please confirm status of all available goods **until 25.09.2020**

Please kindly complete and return the attached response forms to your contact.

Your internal contact for further information is [REDACTED], telephone: (+49) 7321 – 36 [REDACTED].

Transmission of this Urgent Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected products have been transferred to. Therefore, please take adequate measures. A template for a customer letter is enclosed. Customers are requested to confirm receipt of the Urgent Field Safety Notice to the local HARTMANN affiliate of Croatia.

Due to regulatory reasons we do require your written confirmation of implementation and closing of the Field Safety Corrective Action above.

This Urgent Field Safety Notice has been submitted to the Competent Authorities of the concerned countries within the European Economic Area (EEA). In countries outside the EEA the respective affiliate is responsible to fulfil the relevant notification duties.

Heidenheim, September, 1st 2020

PAUL HARTMANN AG

[REDACTED]

Attachments:

1. List of affected products
2. Response form 1 Affiliate Reception & Transmission 01.09.2020
3. Response form 2 Affiliate Closure 01.09.2020
4. Customer letter affiliate including response form Customer Reception & Transmission 01.09.2020

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