

PAUL HARTMANN AG
Paul-Hartmann-Strasse 12
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Germany

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hartmann.info



Urgent Field Safety Notice

Instructions to Affiliate

Field Safety Correction Action: Voluntary Product Recall

Trade name: Zetuvit® E 10cm x 10cm P50 (unsterile)

Article number / LOT: 413860 / 100301137 (according to attachment 1)

September 17th, 2021

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

Affected product: Zetuvit® E 10cm x 10cm P50 (unsterile) (see attachment 1)

Description of the problem and Product Advisory Notice:

Zetuvit® E is an unsterile single use absorbent pad, made of smooth cellulose fibers (fluff); covered on the backside by a hydrophobic nonwoven, being water repellent and permeable to air; together surrounded by a cellulosic tissue layer for secretion distribution; the whole is wrapped in a non-adherent and hydrophilic nonwoven. The backside is characterized by a blue coloured thread.

During our internal routine controls regarding the bioburden - microbiological load (according to DIN EN ISO 11737 Part 1: 2018-11) of our non-sterile products, a deviation was detected. Here, bacteria were identified, which are not desired in medical products. An infection risk cannot be excluded entirely when using the named product. Our preliminary investigations suggest that this is an entry through raw materials by our suppliers.

This only concerns the above-mentioned non-sterile product, the sterile products (Zetuvit®, Zetuvit® E) are not affected.

The affected product / LOT was immediately set under quarantine in our warehouses.

ILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück
(Vorsitzende des Vorstands/CEO), François Georgelin,
Stefan Grote, Dr. Raymund Heinen, 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
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Up to this point of time neither complaints nor (serious) incidents were registered concerning the described issue.

For the PAUL HARTMANN AG safety of patients, users and third parties have the highest priority. Therefore, we voluntarily recall the product **Zetuvit® E 10cm x 10cm P50** (article number: 413860 / LOT: 100301137).

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 Thursday, 07.10.2021.**

For confirmation of closure please complete and return attachment 3 (Response form 2 Affiliate Closure) **until Thursday, 21.10.2021.**

Response form 1: Affiliate Reception & Transmission to confirm having informed all respective people and organizations of this urgent field safety notification **until 07.10.2021.**

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 21.10.2021.**

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.

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

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Helps. Cares. Protects.

This Urgent Field Safety Notice has been submitted to the Competent Authorities of the concerned countries within the European Economic Area (EEA).

Heidenheim, September, 17th 2021

PAUL HARTMANN AG



Attachments:

1. Product list
2. Response form 1 Affiliate Reception & Transmission 17.09.2021
3. Response form 2 Affiliate Closure 17.09.2021
4. Customer letter affiliate including response form Customer Reception & Transmission 17.09.2021

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