Mustermann
Musterstraße
Musterort

BAUERFEIND AG • TRIEBESER STR. 16 • 07937 ZEULENRODA-TRIEBES

June 27, 2024

Urgent Safety Information

Recall

concerning

<VenoTrain micro> medical compression stockings

and <AchilloTrain> supports

ANSCHRIFT
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Sender:

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Recipient:

Medical supply retailers, pharmacists

Identification of affected medical devices:

Medical compression stockings: <VenoTrain micro>

Supports: <AchilloTrain>

We are individually notifying the relevant customers with a list of products affected by the recall and their item numbers.

Description of the issue including the identified cause:

Problem and cause: this week, during construction work on the roof (drilling through the roof of the production hall), small metal shavings fell into Bauerfeind AG's Production Area. Unfortunately, we cannot be sure that these metal shavings did not get into the production process, contaminating some products.

Risks for patients: it cannot be ruled out that metal shavings have become attached to products, which may rub on the skin when the products are being worn. This may result in the user's health being affected.

What action does the recipient need to take?

All affected medical retailers and pharmacies will receive "Urgent Safety Information" from Bauerfeind AG.

If products have already been handed to patients, the recipient must contact the patient immediately so the product can be returned. These products must be returned to Bauerfeind straight away. They must not be destroyed onsite.

If the ordered goods have not yet been handed to patients, the recipient must return the items to Bauerfeind without delay. They must not be destroyed onsite.

Returns are handled in accordance with Bauerfeind AG's Returns Policy which allows a credit note or replacement.

Schedule:

- during calendar week 27, all affected medical retailers and pharmacies will be notified: in writing via "Urgent Safety Information"
- All products must be returned by the end of calendar week 30.
- During calendar week 31, the closing report will be submitted to the relevant authority.

Contact:

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