

URGENT field safety notice

Recall on affected devices

Infusion tube for syringe pumps 150 cm

Date: 06.05.2024

Issuer/ Manufacturer:

*Shandong Lee Med Technology Co., Ltd.
No. 10, Sanying Road, Technology Industrial Park
Zhangdian District, Zibo, 255000 Shandong*

Addressee: customers of the EU Importer, which received the affected batch.

Model	Reference	Description	Batch/ LOT	EXP
17-PL-15150	P7101T-150	Infusion tube for syringe pumps 150 cm	23/502679	2028-03-30

Description of the product problem and the probability of problem arising:

In a user report, it was determined that the designated product „ *Infusion tube for syringe pumps 150 cm* “, model P7101T-150 of the batch 23/502679, the connection from the tube to the connector is leaking.

The error has not been reproduced by the manufacturer.

Based on the results of internal tests at the manufacturer as well as the EU importer, the defect can be limited to the batch 23/502679 of this product. So far, no other size or batch of this product is affected. As a precaution, the whole batch of this product is recalled.

Action To Be Taken by the User:

1. Check all stocked products for the affected REF-Code and Batch-numbers.
2. Forward this information to any other party, that you supplied this product to (i.e., your customers).
3. If you or your customer(s) have any affected goods in your stock, please ensure that the relevant products are quarantined and no longer in use.
4. Please provide feedback regarding your stock via the link below until June 6th 2024.
5. **Please destroy your affected stock.** By sending your report-form you confirm the accuracy of your reported quantities as well as their destruction. Please implement the measures immediately.
6. You will receive a credit memo from Wolfram Droh GmbH for the destroyed stock.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

The German federal institute for pharmaceuticals and medical products has received urgent field safety notice.

Contact EU-importer:

Wolfram Droh GmbH

Guido Schuth

Phone: +49 6131 623 19 21

Fax: +49 6131 623 19 10

E-Mail: g.schuth@droh.de

We regret the inconvenience caused and apologise for this.

Yours sincerely