



URGENT FIELD SAFETY NOTICE

Colour Coded Syringes

07.11.2025

By: MedNet GmbH, Borkstrasse 10, 48163 Münster, Germany

For attention of: Manufacturers of medical devices and CPT providers

Affected products and lot number range:

Part number	Product description	Lot
10301200	Colour Coded Syringe, 10ml, LL, Polycarbonate, red	P2342004
10301400	Colour Coded Syringe, 10ml, LL, Polycarbonate, blue	P2416002

Description of product problem:

MedNet GmbH is issuing this urgent field safety notice after contamination with particles was identified in some syringes.

Particles may not be detectable before use due to the potential for the particle to adhere to the syringe seal; therefore, in the worst-case scenario, their use on patients could lead to an embolism.

Investigations in the production environment have revealed that 90% of the specified batches are not affected. For the remaining 10%, contamination cannot be definitively ruled out. Therefore, the aforementioned batches are being recalled in their entirety.

Actions to be taken:

To support this recall and ensure that the affected products are removed from the market, please take the following steps:

- Check if any of the affected products listed are in your warehouse.
- Enter your inventory on the following list and immediately stop all further shipments of the affected product.
- Please send the completed confirmation form and the completed list to nicole.boehnisch@medneteurope.com as soon as possible, but no later than five (5) days after receiving this letter, even if you no longer have any stock.
- Upon receipt of the completed confirmation form, your account manager will contact you to arrange disposal/collection.
- Forward this safety information to all customers who have received the affected product.



Please send us your confirmation that this recall has been communicated to all economic operators who have received products from you as listed below.

We also ask that you ensure the remaining stocks from the economic operators are returned to you so that we can then coordinate the next steps with you.

We rely on your cooperation to process this. We apologize for any inconvenience and thank you for your cooperation.

The relevant competent authority in your respective country has been informed about this urgent field safety notice.

With best regards,

XXX
General Manager

XXX
Quality Management/Regulatory Affairs

Annexes:
Annex 1 – Confirmation



RECALL CONFIRMATION FORM

Recall of Color-Coded Syringe

Attachment 1: Acknowledgement of Product Recall

Please send the completed confirmation form and the completed list as soon as possible, but no later than five (5) days after receiving this letter, to nicole.boehnisch@medneteurope.com.

Name (Company): _____

Customer Number: _____

Name (Person): _____

Date: _____

<input type="checkbox"/> YES - We have reviewed inventory of the products mentioned in the recall letter and have quarantined the affected products.	Please enter the quantity of affected products into the list
<input type="checkbox"/> NO - We do not have any of the products mentioned in the recall letter in stock.	
<input type="checkbox"/> Economic actors downstream in the supply chain have been informed by us about the recall and have quarantined the affected products.	Please enter the quantity of affected products into the list
<input type="checkbox"/> We have informed the following economic players in the supply chain about the recall and they DO NOT have any of the affected products in stock according to the list.	

Date / Stamp / Signature _____

Note: This form confirms receipt of an electronic version.