

## Field Safety Corrective Action: Product Recall

**Product Codes:** LHE01LD LHE25LD LHE05 OT005 OT01 OT25 OT05 OTH01 OTH25 OTH05  
**Brands:** Medicina ENfit reusable enteral syringes  
Medicina single-use and reusable oral tip syringes  
**Ref:** FSN-007  
**Date:** 15 June 2022

### Field Safety Corrective Action notice for certain batches of Medicina ENfit reusable syringes and Medicina single-use and re-usable oral syringes.

#### Immediate Attention

All users of Medicina ENfit reusable syringes and Medicina single-use and re-usable oral tip syringes.

#### Device Description

Medicina ENfit reusable enteral syringes and Medicina single-use and reusable syringes are used to deliver nutrition and medication.



Medicina Single Use and Reusable Oral Tip Syringes



Medicina ENFit reusable Low Dose enteral syringes



Medicina ENFit reusable enteral syringes

#### Reason for product recall

Medicina is voluntarily recalling the batches of product listed below because the plunger component has been manufactured with an unapproved material. We would like to reassure users that material that was used is safe for the intended use, however it does not meet our raw material specification, and this is the reason for the recall.



**Recalled Product Code, Description and Batch Numbers**

Code	Description	Batches
LHE01LD	ENFit 1ml Reusable Low Dose Enteral Syringe	HM17121, HM18051, HM18080, HM18120, HM18141, HM19007, HM19016, HM19059, HM19083, HM19130, HM19144, HM20005, HM20054, HM21044, HM22018
LHE05	ENFit 5ml Reusable Enteral Syringe	HM17099, HM18010, HM18052, HM18103, HM18113, HM18143, HM19009, HM19018, HM19061, HM19084, HM19132, HM19146, HM20006, HM20032, HM20055, HM20095, HM21037, HM21069, HM22019
LHE25LD	ENFit 2.5ml Reusable Low Dose Enteral Syringe	HM18022, HM18095, HM18121, HM18142, HM19008, HM19017, HM19060, HM19131, HM19145, HM19167, HM20014, HM20031, HM20049, HM21033, HM22008
OT005	Oral Tip Syringe 0.5ml	HM19024
OT01	Oral Tip Syringe 1ml	HM18147, HM19012, HM19025, HM19088, HM19164, HM20063, HM21015, HM21072
OT05	Oral Tip Syringe 5ml	HM19027, HM21073, HM22008
OT25	Oral Tip Syringe 2.5ml	HM19026, HM19165, HM20019, HM20064, HM21061
OTH01	Reusable Oral syringe 1ml	HM18041, HM21053
OTH05	Reusable Oral syringe 5ml	HM18043, HM20020, HM21055
OTH25	Reusable Oral syringe 2.5ml	HM18042, HM21019, HM21054

**Corrective Action**

New product is being manufactured which meets our specification.

**Action to be taken**

- Please carefully read this Field Safety Notice and return the Acknowledgement Form
- Please do not use any of the batches of product listed on this notice
- If you have product to return, please complete the information on the Acknowledgement Form and our team will arrange the return for you
- Please distribute throughout your organisations and to relevant personnel
- If you have any questions or queries in relation to this notice, please contact us using the information below

**Contact information regarding FSN**

Shaista Patel  
 QA/RA Administrator  
 Unit 2, Rivington View Business Park, Station Road, Blackrod, Bolton  
 BL6 5BN  
 Email: [quality.administrator@medicina.co.uk](mailto:quality.administrator@medicina.co.uk) Tel: 01204 695050



## **Acknowledgement Form: FSN 007 Field Safety Corrective Action**

**Product Codes:** LHE01LD LHE25LD LHE05 OT005 OT01 OT25 OT05 OTH01 OTH25 OTH05

**Brands:** Medicina ENfit reusable enteral syringes  
Medicina single-use and reusable oral tip syringes

Please confirm you have received the notice by completing this form and returning it to us by post or email as soon as possible.

### **Acknowledgement**

We confirm receipt of this Field Safety Notice – FSN 007 and that this is received, read, and distributed to anyone it may concern within our organisation and/or to our customers (for distributors).

<b>Organisation Name:</b>	
<b>Department:</b>	
<b>Representative Name and Signature:</b>	
<b>Date:</b>	
<b>Product to be returned:</b>	Yes / No
<b>Contact details to arrange return:</b>	

### **Please return to:**

Shaista Patel  
QA/RA Administrator  
Unit 2, Rivington View Business Park, Station Road, Blackrod, Bolton  
BL6 5BN  
Email: [quality.administrator@medicina.co.uk](mailto:quality.administrator@medicina.co.uk) Tel: 01204 695050 Fax: 01204 697755

