

## URGENT FIELD SAFETY NOTICE Voluntary Medical Device Recall

Date: 22<sup>nd</sup> August 2019

MHRA Ref: 2019/008/022/601/002

Medicina FSCA Ref: FSN22082019 – 005

### Description of the Problem:

Medicina Ltd is conducting a voluntary recall for one batch of their Intravenous Syringes as detailed below:

Medicina Product Code	Product Description	Batch Number	Expiry Date
IVS03	3ml IV Luer Slip syringe without needle	19040303	2024-04

### Reason for Recall:

One instance has been reported of a non-Medicina syringe with a needle in Medicina packaging. This product is supplied without a needle. As a precautionary measure, Medicina are conducting a voluntary product recall on this batch.

### NO OTHER MEDICINA PRODUCTS, OR BATCHES, ARE AFFECTED BY THIS RECALL

#### Conforming - Product



#### Defective Product



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Registered Office  
Unit 2, Rivington View Business Park, Station Road, Blackrod, Bolton BL6 5BN  
Tel: 01204 695050 Fax: 01204 697755 email: [info@medicina.co.uk](mailto:info@medicina.co.uk) [www.medicina.co.uk](http://www.medicina.co.uk)

Medicina Ltd. A Company registered in England and Wales Reg. No. 2654669



### Location of Batch and Expiry Date



### Recommended Action to be taken by affected customers:

1. Cease use of affected batch as described within this recall notice on page 1.
2. Segregate this product in a secure location for return Medicina or your distributor.
3. Please forward this information for the immediate attention of the persons responsible for usage of the affected product. A sub-recall must be initiated by your company to collect any unused and affected products from your affected customers.
4. Please complete the attached FSCA Acknowledgement Form and indicate the quantity of the affected product and in your possession.
5. Promptly return the completed FSCA Acknowledgement Form to Medicina and your distributor (where applicable) by e-mail.

### Contact reference person for Field Safety Notice:

Name: Caterina Buono, Quality Administrator  
Email: [Quality.Administrator@medicina.co.uk](mailto:Quality.Administrator@medicina.co.uk)  
Fax: 01204 697755

Company: Medicina Ltd  
Address: Unit 1 -4 Rivington View Business Park, Station Road, Bolton BL6 5BN, UK  
Phone Number: 01204 357588

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Peter Smith  
Quality Assurance and Regulatory Affairs Manager  
Medicina (UK) Ltd

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**FSCA ACKNOWLEDGEMENT FORM**

Please complete this form and return to Medicina or your distributor as follows:

Email: [Quality.Administrator@medicina.co.uk](mailto:Quality.Administrator@medicina.co.uk)

Stock Status		<input type="checkbox"/> I do not have the affected lot in Stock <i>(please place "0" in the Quantity for Return column)</i> <input type="checkbox"/> I have the affected lot in Stock	
Medicina Product Code	Product Description	Batch Number	Quantity for Return (Singles)
IVS03	IV Luer Slip syringe	19040303	
<b>Name of the Organisation who Supplied you the Product:</b>			
<b>Your Organisation:</b>			
Completed by (Name):			
Department:			
Position/ Job title:			
Sign:		Date:	

*\*Where applicable complete more than one sheet*

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