

04 July 2022

Dear Martina, Sebastien and Markus,

Further to the attached Field Safety Corrective Action notice, we are writing to confirm to you the batches of product you have received that are impacted by this notice.

We would also like to reassure you that the following products are **not** impacted by this notice:

Medicina ENfit Single Use (Sterile) Enteral Syringes

All Sizes (LPE01LD, LPE25LD, LPE05, LPE10, LPE30, LPE60, LPE100)

Medicina ENfit Reusable (Non-Sterile) Syringes

Sizes 10ml, 20ml, 60ml (LHE10, LHE20, LHE60)

Medicina Oral Tip Single Use (Sterile) Syringes

Sizes 1ml low dose, 25ml low dose, 10ml and 20ml (OT01LD, OT25LD, OT10, OT20)

Medicina Oral Tip Reusable (Non-Sterile) Syringes

Sizes 10ml and 20ml (OTH10, OTH20)

As stated in the FSCA, whilst the material used has been tested in accordance with the requirements for the intended use of the syringes and met those requirements, it is not the approved material. In order to conform to our current certification, which cannot be changed under MDD at present, we are recalling the product.

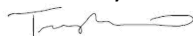
We apologise for the inconvenience caused and will assist you as far as is possible whilst replacement product is manufactured.

To assist you in the recall process, the table below provides details of the products you have received that are being recalled.

Code	Batch	Boxes	Syringes
LHE25LD	HM20049	100	10000
LHE25LD	HM21033	380	38000

Please do not hesitate to contact us if you have any queries or concerns.

Yours sincerely



Tracey Macdonald
Managing Director

