



SPECIALISING IN BIOMATERIALS

Medira Ltd
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14 April 2022

Dear valued Customer

VOLUNTARY RECALL OF A LIMITED NUMBER OF PRP TUBES (PPT-1) BY ESTAR TECHNOLOGIES

This letter serves to offer an explanation and unconditional assurance to you, our valued customers, that PRP products supplied by Medira Limited in the United Kingdom and Ireland, and manufactured by Estar Technologies Limited have not been the subject of the product recall initiated by Estar Technologies, in consultation with the FDA.

A supply of Platelet preparation tubes (PPT-1) was isolated to a batch supplied to two Eclipse PRP distributors in the USA and was well managed within the scope of Estar Technologies rigorous quality control recall procedures. Due to the rapid response by Estar Technologies and Eclipse PRP distributors, only 1000 tubes needed recalling from the market. The remainder of the shipment had not been released to customers.

Risk to Health:

Eclipse, the US product distributor, has not received any complaints from customers regarding the distributed tubes that had been received. Neither have any reports of an adverse event been received by the FDA.

The MHRA has been supplied with Estar documentation regarding this voluntary recall and are satisfied with the assurance these documents provided. The Risk Assessment for the level of contamination present was "localized erythema" or "pain/tenderness at the injection site".

Medira Limited would like to assure our customers in the United Kingdom and Ireland that under no circumstances, were any of the product batches identified for the recall, received by our company. In line with our own ISO9001 quality assurance compliance, there would have been strict oversight.

We are aware that there are alerts being circulated by email and on social media, making inflammatory statements about this limited and specific recall of product. These notifications have no merit and do not impact the supply of PRP products manufactured by Estar Technologies to the UK and Ireland by Medira Limited.

Medira Ltd Registered Office:

St John's Innovation Centre, Cowley Road, Cambridge CB4 0WS

Company Number: 6540217. VAT Number: GB931371637



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Be aware as well, that mention of Chinese manufacture or any other PRP product in the same alert, have nothing whatsoever to do with Estar Technologies product.

If you have any questions or require further details regarding this matter, please contact me.

Kind regards

Roseanne Aitken
Managing Director

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