

QD004/07 Appendix 01 Version01

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Drug Alert

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

Date: 3rd December 2013

Our Ref: MDR 1-12/13

Dear Healthcare Professional,

B. Braun Melsungen AG

Sodium bicarbonate 8.4% solution for infusion

Batch Number	Expiry Date	Pack Size	First Distributed
120528063	31/12/2013	250ml	30/5/2012
120858065	31/1/2014	250ml	30/5/2012
125018061	30/11/2014	250ml	25/3/2013

Medicinal product pertaining to the above product and the above mentioned batches is being recalled up to pharmacy level by the local distributor under the supervision of the Medicines Authority. This recall is being affected following the receipt of a Rapid Alert Notification stating that 'Precipitation found in retain samples of two batches'.

All stock of these batches is to be immediately quarantined awaiting collection by the local distributor.

Yours faithfully

Muriel Giglio

Medicines Inspector Medicines Authority