

Mandatory Product Recall of Diluent GHI154

Letter to Customers,

To Siemens Customers from MediRox AB, regarding Diluent GHI154, batch no 11398 and 11171

MediRox have decided to withdraw vials of above product and lot number since investigations have confirmed that some of the vials (1.8%) of these batches contain a volume less than specified. The lowest fill found was 0.4µl under stated specification 5.0 mL.

The Diluent is used for reconstituting MediRox Owrens PT, and even if the assessment is that there is no patient health risk using the product, it will cause difficulties with abnormal controls and therefore should no longer be used.

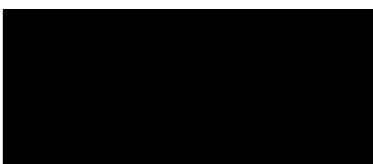
MediRox as legal manufacturer of GHI154 Diluent has therefore initiated a mandatory total recall of the entire lots and will compensate all customers with new products. These lots should no longer be used by any customers.

In case you have no option but to use the product during replacement delivery time, every user is recommended to verify correct volume of 5,0 mL prior reconstitution.

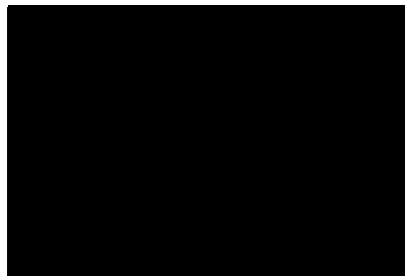
If you have any questions or need assistance with replacement products, please contact your local Siemens representative.

MediRox AB

May 03, 2012



QA Manager



CEO