

## Urgent Field Safety Notice

### Batch Recall of AV-SET B-R for 4008 dialysis machines (Item code F00001124 – Batch code XFV22200)

Date: October 14<sup>th</sup> 2016

Dear customer,

During the continuous market surveillance of our 4008 bloodline tubing systems, we have become aware of blood leakages referring to batch XFV22200.

The leakages were caused by an insufficient gluing of the dialyzer connectors to the blood tubing. Worst case this could lead to a complete detachment of the tube.

**In order to avoid the risk of blood leakages we ask you to immediately stop using the affected product batch XFV22200.**

**Please provide this notice to all those who need to be aware of it within your organization.**

We sincerely apologize for the inconvenience. Aim of Fresenius Medical Care is to provide highest quality products. You will be contacted by your Fresenius Medical Care representative to organize the exchange.

In case of any further questions do not hesitate to contact:

Name: **Please enter local contact**

Telephone: **XXX**

e-mail: **XXX@fmc-ag.com**

Sincerely yours,