



## **Urgent Field Safety Notice**

### **Recall of *Fresenius Medical Care haemodialysis bloodline for 4008 dialysis machine***

Date: **XXXXXXXXXX**

Affected article numbers:

AP16661 AV-Set B DT INF-E  
AP16843 AV-Set DT-E

Affected batch number:

**Enter the batch number based on Annex A and your local receipt/delivery record**

Dear customer,

During the continuous post market surveillance of our haemodialysis bloodlines for 4008 dialysis machine, we have become aware of a potential of increased likelihood of blood leakage between dialyzer connector and tubing for products.

It has been determined that a supplied material used in the dialyzer connector which were manufactured between August 2014 and March 2015 and is causing a weak seal between the connector and tubing, leading to possible leakages. We have corrected this issue with an alternate approved and validated connector material.

**In order to avoid the risk of blood leakage we ask you to immediately stop using the affected products.**

**Please provide this Recall Notice to all those who need to be aware of it.**

You will be contacted by your local Fresenius Medical Care representative to organize the replacement of the affected product.

We sincerely apologize for the inconvenience and we will provide you with new sets as soon as possible. In case of any further questions please do not hesitate to contact:



**FRESENIUS  
MEDICAL CARE**

Name: Please enter local contact

Telephone: XXX

e-mail: XXX@fmc-asia.com

Sincerely yours,