

**Declaration**

**Statement on Substances of Very High Concern  
(SVHC Candidates) in articles acc. to REACH**

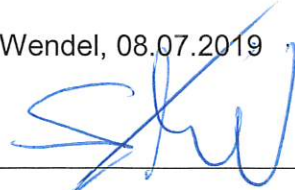
The following product does not contain any SVHC Candidates above the threshold value (0.1 % by weight for each article) according to Article 33 of the European REACH Regulation (Regulation (EC) No. 1907/2006).

Product identification	Comments
<u>FX class Dialysers:</u> - FX paed - FX 5 - FX 10 - FX 60 M, FX 80 M - FX 40 - FX 100 - FX HdF 600 - FX HdF 1000 - FX 50 classix - FX 100 classix - FX CorDiax 40 - FX CorDiax 120 - FX CorDiax HdF 600 - FX CorDiax HdF 1000	--

NB: REACH Article 3/3 defines "articles" as "objects which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition".

This statement represents our current state of knowledge and can be updated at any time. This statement does neither represent a guarantee of any product properties nor releases any party from its responsibilities, especially defined by local legislation. Fresenius Medical Care accepts no responsibility for injury or loss which may arise from reliance on information contained in this document.

Sankt Wendel, 08.07.2019

i.V. 

**Dr. Stefan Sticher**  
 Director Regulatory Affairs & Laboratory Services,  
 Qualified Person  
 Product Line Quality & Regulatory Affairs

Fresenius Medical Care AG & Co. KGaA  
 61346 Bad Homburg – Germany

i.V. 

**Dr. Melina Haben**  
 Material Compliance Expert  
 Chemist  
 Product Line Quality & Regulatory Affairs

Fresenius Medical Care AG & Co. KGaA  
 61346 Bad Homburg – Germany