

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).

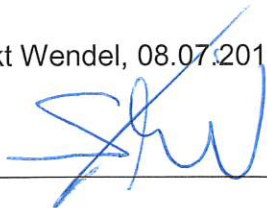
Product identification	Comments
<u>Plasmapheresefilter:</u> - plasmaFlux® - P1dry, plasmaFlux® - P2dry - Monet® - AlbuFlow® AF 01	--

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