

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 under MDD	Product identification under MDR	Comments
<u>PD Catheter</u>		
Tenckhoff Catheter 215	Paed Tenckhoff Catheter, 1 cuff, 25 cm	-
Tenckhoff Catheter 210	Paed Tenckhoff Catheter, 2 cuffs, 25 cm	
Tenckhoff Catheter Straight 516	Tenckhoff Catheter 36 cm	
Tenckhoff Catheter Straight 916	Tenckhoff Catheter 40 cm	
Swan-Neck Catheter Straight 416	Swan-Neck Tenckhoff Catheter 43.5 cm	
Swan-Neck Catheter Straight 419	Swan-Neck Tenckhoff Catheter 47 cm	
Tenckhoff Catheter 835	Tenckhoff Catheter Curled 61.5 cm	
Tenckhoff Catheter coiled	Tenckhoff Catheter Curled 62.5 cm	
Oreopoulos Zellermann 916	Oreopoulos Zellermann Catheter 41 cm	
Swan Neck Catheter Fast flow (coiled)	Swan-Neck Curl Catheter fast-flow 63 cm	
Swan-Neck-Catheter Fast flow 385/195 (coiled)	Swan-Neck Curl Catheter fast-flow 58 cm	
Tenckhoff-Catheter 180	n/a	

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, 29-Oct-2021

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