

Declaration

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

The following product does <u>not</u> 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	Comment
PD Catheter	
Paed Tenckhoff Catheter, 1 cuff, 25 cm	
Paed Tenckhoff Catheter, 2 cuffs, 25 cm	
Tenckhoff Catheter 36 cm	
Tenckhoff Catheter 40 cm	
Swan-Neck Tenckhoff Catheter 43.5 cm	N/A
Swan-Neck Tenckhoff Catheter 47 cm	
Tenckhoff Catheter Curled 61.5 cm	
Tenckhoff Catheter Curled 62.5 cm	
Oreopoulos Zellermann Catheter 41 cm	
Swan-Neck Curl Catheter fast-flow 63 cm	
Swan-Neck Curl Catheter fast-flow 58 cm	

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.

i.V. 27-Arr-2023 Mr. Dr. Markus Krämer

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