

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>Handling devices unsterile</u> <i>stay•safe</i> [®] Holder for Organizer Clip for <i>stay•safe</i> [®] Organizer <u>Handling devices sterilised by ETO</u> Screw Device Luer-Lock <u>Transfer sets sterilised by ETO</u> <i>stay•safe</i> [®] Catheter Extension Luer-Lock 25/32/40/60 cm DISC - <i>Safe•Lock</i> [®] Adaptor <u>Transfer sets sterilised by steam</u> <i>safe•lock</i> [®] APD Luer-Lock Connector <u>Catheter adapter and closure caps sterilised by ETO</u> Catheter Adaptor Luer-Lock with Closure Cap Catheter Adaptor Luer-Lock Closure Cap <i>stay•safe</i> [®] Catheter Adaptor <u>Drainage sets sterilised by steam</u> <i>stay•safe</i> [®] Drainage Set <i>stay•safe</i> [®] Luer-Lock Set <u>Closure caps sterilised by irradiation (Gamma)</u> <i>stay•safe</i> [®] Closure Cap <u>Disinfectant caps containing iodine unsterile</u> <i>stay•safe</i> [®] Disinfection Cap	-

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".



**FRESENIUS
MEDICAL CARE**

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, 13.03.2020

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