

## **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).

Article number	Article name	Comments
MD14011	ACD-A 1000 ml – Safe Lock	-
MD14012	ACD-A 1000 ml – Luer Lock Female	-
MD14021	ACD-A 1000 ml – Correct Connect	-

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 Kabi accepts no responsibility for injury or loss which may arise from reliance on information contained in this document.

Bad Homburg, 08.07.2022

Bert Bolks

R&D Project Manager

Transfusion Medicine & Cell Therapies

Fresenius Kabi MedTech

Sylvia Hondke

Manager Regulatory Affairs

I.V. S. Handlee

Transfusion Medicine & Cell Therapies

Fresenius Kabi MedTech

On behalf of:

Fresenius Kabi AG 61346 Bad Homburg

Germany