Cytiva
Björkgatan 30
751 84 Uppsala
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Statement

Regarding: Latex in Sepax™ C-Pro and Sefia™ S-2000 single use kits and accessories

Background

Natural rubber has been associated with anaphylaxis in individuals allergic to natural rubber latex proteins. This appears to be caused by certain naturally occurring soluble allergenic proteins. The following guidelines have been introduced:

The US Food and Drug Administration

1. User Labeling for Devices that Contain Natural Rubber (21 CFR 801.437) (1 April 2019)
2. Guidance for Industry and Food and Drug Administration Staff - Recommendations for Labeling Medical Products to Inform Users that the Product or Product Container is not Made with Natural Rubber Latex (December 2014)

The European Commission

1. Implications of the Medical Devices Directives (93/42/EEC) in Relation to Medical Devices Containing Natural Rubber Latex: A Guide for Manufacturers and Notified Bodies. MEDDEV 2.5/9 rev. 1 (Feb 2004)

Statement

It is hereby stated that natural rubber latex is not a primary raw material in the products listed below, nor is it intentionally added or introduced during manufacture of these products.

Packaging materials are not made from natural rubber latex.

All products listed below have been tested by an independent third-party laboratory as per ASTM D6499 and did not exhibit latex-specific antigenic proteins above the reporting limit of 0.03ug/ml. Additionally, Cytiva is in the process of retrieving latex-free declarations from all suppliers of wetted components for the below products.

Product/Part name	Product number
CT-49.1 – Sepax cell separation kit - Box of 6 Units	29264738
CT-60.1 – Sepax cell separation kit - Box of 6 Units	29264739
CT-90.1 – Sepax cell separation kit - Box of 6 Units	29264740
CT-300.1 – Sefia cell processing kit - Box of 8 Units	29284866
CT-800.1 – Sefia cell processing kit - Box of 8 Units	20001
CPAK-100 - Box of 60 Units	29275109
CPAK-101 - Box of 60 Units	29275108

Signature: 	Date: 13 February 2023
Name: Henrik Norberg	Title Customer Regulatory Support Leader