

Statement

Regarding: Latex in Sepax™ C-Pro and Sefia Select™ system single use kits and accessories

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:

US Food and Drug Administration (FDA):

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)

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)

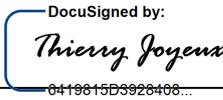
Product/Part name	Product code
CT-49.1 - Sepax cell separation kit - Box of 6 Units	29264738
CT-60.1 - Sepax cell separation kit - Box of 6 Units	29264739
CT-90.1 - Sepax cell separation kit - Box of 6 Units	29264740
CT-200.1 - Sefia cell processing kit - Box of 8 Units	29656477
CT-300.1 - Sefia cell processing kit - Box of 8 Units	29284866
CT-350.1 - Sefia cell processing kit - Box of 8 Units	29660965
CT.400.1 - Sefia cell processing kit - Box of 8 Units	29660968
CT-800.1 - Sefia cell separation kit - Box of 8 Units	20001
PB-100.1 - Cell Processing bag - Box of 10 Units	29660974
CPAK-100 - Box of 60 Units	29275109
CPAK-101 - Box of 60 Units	29275108

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 listed products 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.

Cytiva ensures that all sourced raw materials meet specified requirements and are procured exclusively from qualified suppliers. However, complete information may not always be available from every component supplier to fully address potential contamination risks. While natural rubber latex is not intentionally used by Cytiva or incorporated into supplier-sourced raw materials, the possibility of trace by-products arising from certain manufacturing processes cannot be entirely excluded.

Signature:  0419815D3928408...	Date: 04 March 2026
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