

## Statement

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

It is hereby stated that the products listed below do not present any BSE/TSE risk (animal origin) within components, materials and manufacturing process of components and finished goods which are in contact with the fluid path.

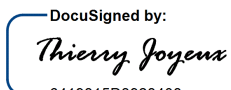
Within the fluid path, animal origin related materials are not primary raw materials in Sepax™ C-Pro and Sefia Select™ system single use kits and accessories, nor are they intentionally added or introduced during manufacture of these products.

Additionally, if traces of animal-derived substances were present within raw materials and/or manufacturing processes, these originate from Category 3 and undergo rigorous production process as described in Annex XIII, Chapter XI of Commission Regulation (EU) No 142/2011, implementing Regulation (EC) No 1069/2009.

Consequently, Sepax C-Pro and Select™ system single use kits and accessories fulfill the requirements of EMA/410/01 Rev.3 (2011/C 73/01) and are free from BSE/TSE risk.

Cytiva declare that purchases of materials conform to specified requirements and are acquired from qualified suppliers. This is achieved through a robust qualification process and thorough supplier monitoring process.

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

Signature:  6419815D3028408...	Date: 25 October 2024
Name: Thierry Joyeux	Title Regulatory Support Manager

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