

Statement

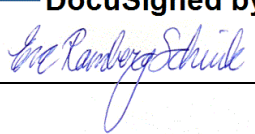

Regarding: Animal origin in Sepax™ C-Pro and Sefia™ S-2000 single use kits and accessories

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™ S-2000 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 Sefia S-2000 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 assures 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-60.1 - Sepax cell separation kit - Box of 6 Units	29264739
CT-90.1 - Sepax cell separation kit - Box of 6 Units	29264740
CT-49.1 - Sepax cell separation kit - Box of 6 Units	29264738
CT-300.1 - Sefia cell separation kit - Box of 8 Units	29284866
CT-800.1 - Sefia cell separation kit - Box of 8 Units	20001
CPAK-100 - Box of 60 Units	29275109
CPAK-101 - Box of 60 Units	29275108

Signature:	DocuSigned by:  <small>DocuSigned by: Eva Ramberg Schink</small>	Date: 9 December, 2021
Name: Eva Ramberg Schink	 E4DDCBC3B91846B...	Title Sr. Regulatory Support Manager

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