

Animal Origin Compliance Statement

Regarding: Bioprocess single-use consumables and filtration products

Background

In plastics manufacturing, animal-derived components are sometimes used as additives to improve material properties, increase lubrication, or aid in the processing of raw materials. Recently, concern has risen that these components may impact the safety profile of medicines that come into contact with these products.

To address this concern, the European Union released a guidance in 2004 entitled "Minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products" (EMA/410/01, rev. 3).

Cytiva does not manufacture human or veterinary medicines but understands that single-use products may be used in the manufacture of finished drugs and drug products.

Statement

Based on statements from our suppliers, the fluid path components of the following products are animal origin free or meet the guidelines outlined in EMA/410/01, rev. 3. Cytiva does not intentionally add animal origin materials during our manufacturing processes.

Single Use Products

- ÄKTA ready™, ÄKTA ready XL, ÄKTA ready 450, ÄKTA readyflux™, and ÄKTA readyflux XL flow kits
- ReadyCircuit™ bags, sensors, jumpers, and filtration assemblies
- ReadyMate™ Disposable Aseptic Connectors (DACs)
- ReadyToProcess™ bags
- ReadyToProcess hollow fiber cartridges
- WAVE™ Cellbags™ and M*bags
- Xcellerex™ assemblies (including XDR, XDM, and X-platform bags)

Filtration Products

- Hollow fiber cartridges
- ULTA™ filters

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General statements, including this one, are available on the Customer Regulatory Support website at www.cytiva.com/rsf. See "Download without a subscription" then "Statements."

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