

# 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). This guidance states that any animal origin derivatives present in a medicinal product were thought unlikely to be infectious when manufactured under conditions listed in section 6.4.

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, ready XL, readyflux™, and 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

#### Filtration Products

- Hollow Fiber Cartridges
- ULTA™ filters

Cytiva appreciates the opportunity to serve our valued customers and is dedicated to improving our capabilities to manufacture and deliver products and services that meet or exceed your needs consistently.

<b>DocuSigned by:</b>	
Signature: 	Date: 14 OCTOBER 2021
Name: Susan Boucher 5300EF5718844C1...	Title: Regulatory Support Manager

The information herein is provided to the best of our knowledge and belief, based on the information we have been given and the information available to us at the time that this document was issued. The information may change as additional facts come to light, or as the circumstances warrant. Your use hereof is hence at your own risk and does not relieve you of your own responsibility for checking the suitability of our products for your intended use.