

Latex Compliance Statement

Regarding: Bioprocess Single-Use Consumables and Filtration Products

Background

Latex allergies are a reaction to certain proteins found in natural rubber latex; a product made from the rubber tree. Latex allergies may cause physical reactions, including anaphylaxis, a potentially life-threatening condition that can cause throat swelling and severe difficulty breathing. With the increased reporting of these adverse reactions to latex, the following regulatory guidance has been introduced:

The US Food and Drug Administration (FDA):

1. "User Labeling for Devices that Contain Natural Rubber (21 CFR 801.437); Small Entity Compliance Guide; Guidance for Industry (1 April 2003)
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)

The European Commission (EU):

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).

Statement

It is hereby stated that natural rubber latex is not a primary raw material in the fluid path of the Cytiva™ bioprocess single-use consumables and filtration products listed below.

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

Additionally, the following manufacturing sites are latex-free manufacturing facilities:

Cytiva Cardiff

Global Life Sciences Solutions Manufacturing UK Limited
1 Longwood Drive
Forest Farm Industrial Estate
Cardiff, United Kingdom
CF14 7HY

Cytiva Cardiff

The Maynard Centre
Longwood Drive
Forest Farm Industrial Estate
Cardiff, United Kingdom
CF14 7YT

Cytiva Eysins

Biosafe S.A.
Route du Petit-Eysins 1
1262 Eysins SWITZERLAND

Cytiva Locke Drive

170 Locke Drive
Marlborough, MA 01752 USA

Cytiva Westborough

14 Walkup Drive
Westborough MA 01581 USA

All Cytiva-approved Contract Manufacturing Organizations (CMOs)

Signature: <i>Susan Boucher</i>	Date: 07 November 2022
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