Cytiva
925 West 1800 South
Logan, Utah 84321
USA

To whom it may concern

Regarding: Latex in HyClone™ Cell Culture Products

Natural rubber has been associated with anaphylaxis in individuals allergic to natural rubber latex proteins. This appears to be caused by certain naturally occurring soluble allergenic proteins. The following guidelines have been introduced:

The US Food and Drug Administration

1. User Labeling for Devices that Contain Natural Rubber (21 CFR 801.437) -- 1 April 2019.
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

1. Medical Device Regulation (MDR) 2017/745 -- 26 May 2021, improves medical device safety in the EU with new classification, design, and surveillance requirements.

It is hereby stated that natural rubber latex is not a primary raw material in Cytiva cell culture products, nor is it intentionally added or introduced during manufacture of these products. However, there is potential for incidental contact with latex from the gloves used by production technicians during the manufacturing process.

- Packaging materials are not made from natural rubber latex.
- Testing for detection of latex in our final products is not performed.

Signature: DocuSigned by: Gerald Dusti McEwen 00773A09EFC74CB...	Date: 09 AUG 2023
Name: Gerald Dusti McEwen	Title Regulatory Support Manager

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