

## To whom it may concern

### Regarding: Compliance statement for cell culture products

Cytiva cell culture products are manufactured at five global sites (listed below). All sites listed are ISO 13485:2016 certified (please refer to each site's certificate for details and registrar).

The Quality Management system complies with ISO 9001:2015 and ISO 13485:2016.

1. Our QMS includes elements from the following: 21 CFR 820; Good Manufacturing Practices (cGMP), 21 CFR 210/211, and ICH Q7.
2. Our QMS consists of, but not limited to management of training, management of change control, complaints, deviations, CAPAs, QA approved batch release, usage of qualified equipment and validated processes within production and QC, raw material is sourced from approved suppliers, qualified before usage and incoming goods inspected.

The intended use of Cell culture products is "For Further Manufacturing or Research Use. Not for Diagnostic or Therapeutic Use." Cytiva cell culture products are not intended for direct administration into human or animals. Customers are responsible for qualifying the raw and starting materials used in their products and assessing the risk associated with their use.

Cytiva cell culture products (HyClone™ brand) are manufactured at five global sites:

HyClone Laboratories LLC  
925 West 1800 South  
Logan, Ut 84321  
USA

***Liquid products, powder products and serum***

Global Life Sciences Solutions Austria GmbH & Co KG  
Krempelstrasse 5  
4061 Pasching  
Austria

***Animal derived component free (ADCF) liquid and powder products***


Global Life Sciences Solutions Singapore Pte.Ltd.  
25 Tuas South Street 1  
Singapore 638034

***Animal derived component free (ADCF) powder products***

Global Life Sciences Solutions New Zealand  
433 Old Highway RD 8  
Tauranga, 3180, New Zealand  
**Serum**

HyClone Laboratories LLC  
8095 S Welby Park Dr.  
West Jordan, UT 84088  
USA  
**Animal derived component free (ADCF) liquid**

The lot number of the product indicates where it was manufactured. Lot numbers beginning with "A" have been manufactured at the Logan, Utah site. Lot numbers beginning with "V" have been manufactured at the Pasching, Austria site. Lot numbers beginning with "M" have been manufactured at the Singapore site. Lot numbers beginning with "D" have been manufactured at the Tauranga, New Zealand site. Lot numbers beginning with "W" are manufactured at the West Jordan, Utah site.

Signature: 	Date:  18 May 2023
Name:  Karen Kiefer	Title  Cell Culture QA Director

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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.

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