

To whom it may concern

Regarding: Compliance statement for cell culture products

Cytiva cell culture products are manufactured at four 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. The cell cultures sites do not claim compliance but includes elements from the following: 21 CFR 820; Good Manufacturing Practices (cGMP), 21 CFR 210/211.
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 are 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 are manufactured at four global sites:

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

Animal Sera/Media/Buffers/Process Liquids


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

Animal Derived Component Free (ADCF) Media/Buffers/Process Liquids

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

Global Life Sciences Solutions New Zealand
433 Old Highway RD 8
Tauranga, 3180, New Zealand
Animal Sera

The lot number of the product indicates where it was manufactured. Lot numbers beginning with "A" have been manufactured at the Logan site. Lot numbers beginning with "V" have been manufactured at the Pasching site. Lot numbers beginning with "M" have been manufactured at the Singapore site. Lot numbers beginning with "D" have been manufactured at the Tauranga site.

Signature: 	Date: 28 March, 2024
Name: Karen Kiefer	Title: Cell Culture QA Director

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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