Cytiva
925 West 1800 South
Logan, Utah 84321
United States of America

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. 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, 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"

The products many be used as a component in the manufacture of a device or drug that requires licensing. It is the responsibility of the device or drug manufacturer or determine if sera and/or cell culture media products are suitable for their application.

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
Kremplstrasse 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
2508 S Welby Park Dr.
West Jordan, UT 84088
Animal derived component free (ADCF) liquid

06 May 2022

Karen Kiefer
Cell Culture QA Director

Date