

Current issue date: Expiry date: Certificate identity number: 11 March 2025 10 March 2028 10676610 Original approval(s): ISO 13485 - 11 February 2025

**Certificate of Approval** 

This is to certify that the Management System of:

## **HyClone Laboratories, LLC**

925 West 1800 South, Logan, Utah, 84321, United States

has been approved by LRQA to the following standards:

## ISO 13485:2016

Approval number(s): ISO 13485 - 00047996

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

## The scope of this approval is applicable to:

Design, manufacture and distribution of consumable cell culture products for application in the medical and life sciences industries.

This certificate is a continuation of a previous approval from another certification body as follows:

Previous original ISO 13485 approval on 11-Mar-2019, Intertek certificate number 0116487-01

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David Derrick

Regional Director, UKAM

Issued by: LRQA Limited



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Certificate identity number: 10676610

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925 West 1800 South, Logan, Utah, 84321, United States	<b>ISO 13485:2016</b> Manufacture of consumable cell culture products for application in the medical and life sciences industries. Despatch/distribution of consumable cell culture products	L
	for application in the medical and life sciences industries.	L
2780 N 200 W, Suite A, Logan, 84321, United States	<b>ISO 13485:2016</b> Design and development of consumable cell culture products for application in the medical and life sciences industries. Manufacture of single use bags for the consumable cell culture products for application in the	L
	medical and life sciences industries.	L
917 W 600 N, Suite 114, Logan, Utah, 84321, United States	<b>ISO 13485:2016</b> Filtration of consumable serum cell culture products for application in the medical and life sciences industries.	L
3135 N 300 W, Hyde Park, Logan, Utah, 84321, United States	ISO 13485:2016 Warehousing of consumable cell culture raw materials for application in the medical and life sciences industries.	L
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