# CERTIFICATE OF REGISTRATION

This is to certify that

## Lifecycle Biotechnologies, LP

5858 Wright Drive, Loveland, Colorado 80538, USA

operates a

## Quality Management System

which complies with the requirements of

## ISO 13485:2016

for the following scope of certification

**Manufacture of general purpose reagents, dissolution media, buffers, and biologicals.**

| | | | |
|---|---|---|---|
| Certificate No.: | CERT-0119062 | Original Certification Date: | April 19, 2013 |
| File No.: | 1633832 | Certification Effective Date: | August 20, 2020 |
| Issue Date: | August 24, 2020 | Certificate Expiry Date: | May 17, 2021 |

Heather Mahon
Global Head of Technical Services
SAI Global Assurance

ISO 13485

# CERTIFICATE OF REGISTRATION

This is to certify that

## Lifecycle Biotechnologies, LP

5858 Wright Drive, Loveland, Colorado 80538, USA

operates a

## Quality Management System

which complies with the requirements of

## ISO 9001:2015

for the following scope of certification

**Manufacture of laboratory reagents, dissolution media, buffers and biologicals.**

| | | | |
|---|---|---|---|
| Certificate No.: | CERT-0135939 | Original Certification Date: | April 19, 2013 |
| File No.: | 1633832 | Certification Effective Date: | July 12, 2020 |
| Issue Date: | July 22, 2020 | Certificate Expiry Date: | May 17, 2021 |

Heather Mahon
Global Head of Technical Services
SAI Global Assurance

ISO 9001

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https://www.saiglobal.com/en-us/assurance/auditing_and_certification/certification_registry/

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# CERTIFICATE OF REGISTRATION

This is to certify that

## Lifecycle Biotechnologies, LP

4343 Industrial Center Drive, San Antonio, Texas, 78217, USA

operates a

## Quality Management System

which complies with the requirements of

## ISO 9001:2015

for the following scope of certification

**Provision of contract blow mold services to life science and industrial manufactures.**

| | | | |
|---|---|---|---|
| Certificate No.: | CERT-0134022 | Original Certification Date: | January 18, 2017 |
| File No.: | 1683314 | Certification Effective Date: | January 17, 2020 |
| Issue Date: | January 17, 2020 | Certificate Expiry Date: | January 16, 2023 |

Heather Mahon
Global Head of Technical Services
SAI Global Assurance

ISO 9001

**Registered by:**
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SAI GLOBAL
INFORM. INSPIRE. IMPROVE.

Dear Michelle Stahla-Quintana:

This e-mail provides confirmation that the annual registration for the following medical device establishment has been successfully completed for 2021:

Registration Number: 3010877980
Owner Operator Number: 10049711
Lifecycle Biotechnologies, LP
5858 Wright Dr
Loveland, CO 80538
UNITED STATES

If you do not see a registration number assigned to the establishment and your establishment previously had one, please send an email to reglist@cdrh.fda.gov and include the registration number you believe is assigned to your establishment. We will review and determine if a duplicate registration has been created for your establishment.

Your registration is valid until December 31, 2021. Registration for 2022 will be conducted between October 1 and December 31, 2021.

Please note that registering your device facility and listing your devices does not, in any way, constitute FDA approval of your facility or your devices.

Should you have any questions, please send an e-mail to the CDRH Registration and Listing Helpdesk at reglist@cdrh.fda.gov.

CDRH Registration and Listing Helpdesk
Imports & Registration and Listing Team
Division 2 Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Tel: 301-796-7400, Option 1
Email: reglist@cdrh.fda.gov

**United States Department of Agriculture**

Animal and Plant Health Inspection Service

Veterinary Services

VETS

Sacramento Service Center

vscoexport@usda.gov

July 1, 2020

Ms. Michelle Stahla
Lifecycle Biotechnologies, LP
5858 Wright Drive
Loveland, CO 80538

Dear Ms. Stahla,

Lifecycle Biotechnologies, LP was inspected on June 24, 2020, and has been granted reference number CO-INT-0002 as being compliant with Regulation (EC) 142/2011 as amended. Please note that this approval is for:

Country/Region: European Union
Facility Name: LIFECYCLE BIOTECHNOLOGIES, LP
Approval Number: CO-INT-0002

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APHIS DOES NOT ENDORSE ANY DOCUMENTS BASED UPON THIS APPROVAL. THIS APPROVAL IS NOT FOR ANY OTHER PURPOSE OTHER THAN TO VERIFY THAT THE FACILITY IS:

APPROVED TO SHIP INTERMEDIATE PRODUCTS TO THE EU ACCOMPANIED BY THE REGULATION (EU) 142/2011 CHAPTER 20 "DECLARATION FOR THE IMPORT FROM THIRD COUNTRIES AND FOR THE TRANSIT THROUGH THE EUROPEAN UNION OF INTERMEDIATE PRODUCTS TO BE USED FOR THE MANUFACTURE OF MEDICINAL PRODUCTS, VETERINARY MEDICINAL PRODUCTS, MEDICAL DEVICES FOR MEDICAL AND VETERINARY PURPOSES, ACTIVE IMPLANTABLE MEDICAL DEVICES, IN VITRO DIAGNOSTICS MEDICAL DEVICES FOR MEDICAL AND VETERINARY PURPOSES, LABORATORY REAGENTS AND COSMETIC PRODUCTS" SIGNED BY THE EU IMPORTER.

Please include the facility's approval number on future correspondence with this office regarding this approval. In order to retain this approval, you must complete the entire approval process at least every 365 days.

To initiate the renewal process, please contact this office at least two months prior to the expiration date of **June 24, 2021**.

Please let me know if you have any questions or concerns.

Sincerely,

CHRISTINA KRASILINEC

Digitally signed by CHRISTINA KRASILINEC
Date: 2020.07.01 10:54:30 -06'00'

Veterinary Medical Officer