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

Registered by:
QMI-SAI Canada Limited (SAI Global), 20 Carlson Court, Suite 200, Toronto, Ontario M9W 7K6 Canada. This registration is subject to the **SAI Global** Terms and Conditions for Certification. While all due care and skill was exercised in carrying out this assessment, **SAI Global** accepts responsibility only for proven negligence. This certificate remains the property of **SAI Global** and must be returned to them upon request.
To verify that this certificate is current, please refer to the **SAI Global** On-Line Certification Register:
https://www.saiglobal.com/en-us/assurance/auditing_and_certification/certification_registry/

SAI GLOBAL
INFORM. INSPIRE. IMPROVE.

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:
QMI-SAI Canada Limited (SAI Global), 20 Carlson Court, Suite 200, Toronto, Ontario M9W 7K6 Canada**.** This registration is subject to the **SAI Global** Terms and Conditions for Certification. While all due care and skill was exercised in carrying out this assessment, **SAI Global** accepts responsibility only for proven negligence. This certificate remains the property of **SAI Global** and must be returned to them upon request.
To verify that this certificate is current, please refer to the **SAI Global** On-Line Certification Register:
https://www.saiglobal.com/en-us/assurance/auditing_and_certification/certification_registry/

SAI GLOBAL
INFORM. INSPIRE. IMPROVE.

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, 2020. Registration for 2021 will be conducted between October 1 and December 31, 2020.

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

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