



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-0139960
File No.: 1633832
Issue Date: May 13, 2021

Original Certification Date: April 19, 2013
Certification Effective Date: May 17, 2021
Certificate Expiry Date: May 16, 2024

Frank Camasta
Global Head of Technical Services
SAI Global Assurance



ISO 13485



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/





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 general purpose reagents, dissolution media, buffers and biologicals.

Certificate No.: CERT-0139959
File No.: 1633832
Issue Date: May 13, 2021

Original Certification Date: April 19, 2013
Certification Effective Date: May 17, 2021
Certificate Expiry Date: May 16, 2024

Frank Camasta
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/



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

July 1, 2020

Veterinary
Services

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

VETS

Sacramento
Service Center

Dear Ms. Stahla,

vscoexport@usda.gov

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



Safeguarding American Agriculture

APHIS is an agency of USDA's Marketing and Regulatory Programs
An Equal Opportunity Provider and Employer

Federal Relay Service
(Voice/TTY/ASCII/Spanish)
1-800-877-8339