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	Original Certification Date:	April 19, 2013
File No.:	1633832	Certification Effective Date:	May 17, 2021
Issue Date:	May 13, 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/

SAI GLOBAL
INFORM. INSPIRE. IMPROVE.

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	Original Certification Date:	April 19, 2013
File No.:	1633832	Certification Effective Date:	May 17, 2021
Issue Date:	May 13, 2021	Certificate Expiry Date:	May 16, 2024

Frank Camasta
Global Head of Technical Services
SAI Global Assurance

ISO 9001

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

Colorado Area Office

13922 Denver West Parkway
Suite 100-VS
Lakewood, CO 80401

Voice:
(303) 859-4985

Fax:
(303) 231-5390

Email:
VSPSID@usda.gov

August 31, 2021

Lifecycle Biotechnologies, LP
Attn: Michelle Stahla-Quintana
5858 Wright Drive
Loveland, Colorado 80538

Dear Ms Stahla-Quintana:

The following facility was inspected on July 19, 2021 for compliance with Regulation (EU) 142/2011:

Lifecycle Biotechnologies, LP
5858 Wright Dr
Loveland, CO 80538

This facility has been approved by APHIS to conduct the following activities related to Regulation (EU) 142/2011:

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

LISTED 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.

TRACES VII 1,2,3 6/27/2020

The facility has been granted APHIS Reference Number: CO-INT-0002.
This exact number should be included on future correspondence with this office regarding this approval. This number may not utilize to indicate that APHIS has approved the facility or products for other purposes.

Please note that the approval is in effect for one year following the last validated inspection and must be renewed annually. In order to retain this approval, the facility must continue to operate under the information provided during the approval process. The facility is subject to unannounced compliance inspections throughout the year to verify this continued compliance.

Lastly, I would like to remind you that the facility must complete the renewal process no later than July 19, 2022. Please contact this office no later than three months prior to this date to initiate re-approval process.

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

Sincerely,

Kyran Cadmus, DVM MPH
Veterinary Medical Officer