DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax: (510) 337-6702	6/1/2026-6/3/2026
	FEI NUMBER 3013944123

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Travis Byrd, Site Operations Manager

FIRM NAME	STREET ADDRESS
Infinity Labs SD, Inc	1836 Stone Ave
CITY, STATE, ZIP CODE, COUNTRY San Jose, CA 95125-1306	TYPE ESTABLISHMENT INSPECTED Contract Sterilizer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Measuring equipment was not calibrated at specified intervals or prior to use.

Specifically,

A) Your firm uses the (b) (4) to interpret biological indicator (BI) results — specifically, to determine positive or negative microbial growth — following a (b) (4) incubation period as part of your (b) (4) sterilization process verification. The (b) (4) output directly supports product quality release decisions. Your firm has (b) (4) units in service (S/N: (b) (4), and (b) (4)), all of which have been used as part of the product release process for at least seven years. Despite this, your firm has never established a calibration or verification program to confirm that the core detection mechanism — the function responsible for determining positive or negative BI growth — continues to operate accurately and reliably. Your procedure SOP-038, (b) (4) *Re-qualification Operation Procedure*, Revision F, is insufficient to address this gap. The procedure only verifies that the (b) (4) maintains the appropriate incubation temperature; it does not verify the accuracy or continued performance of the detection mechanism used to interpret BI results. Without adequate calibration or verification of this critical function, your firm cannot demonstrate that sterilization cycle effectiveness is being reliably confirmed prior to product release.

B) Your firm uses the (b) (4) Temperature Recorder (S/N: (b) (4)) to monitor temperature in one or more critical areas, which may include one of (b) (4) incubators, the biological

indicator storage area, the (b) (4) storage area, or the sterilizer room. Temperature monitoring in these areas is directly relevant to the integrity of your sterilization process and associated materials. Per your equipment log FRM-124, *Equipment Calibration/PM Schedule*, this device was due for calibration on March 19, 2026. However, the device was not sent out for calibration until April 15, 2026, resulting in a lapse period of approximately 27 days beyond the required calibration date. Your firm was unable to provide evidence that the (b) (4) was placed out of service or quarantined during this lapse period. Without such evidence, it cannot be confirmed that the device was not actively used for temperature monitoring while in an out-of-calibration status, raising concerns about the reliability of temperature data recorded during this interval and any associated product or process decisions made during that time.

OBSERVATION 2

Corrective action procedures defining the requirements for reviewing nonconformities have not been adequately documented.

CAPA 25002 documents a missed scheduled preventive maintenance and calibration for one of your firm's (b) (4) Sterilizer (b) (4) units, resulting in a lapse period of at least two months. Per your procedure SOP-018, *Validation, Calibration, and Maintenance*, Section 7.6.2, this sterilizer is required to undergo preventive maintenance and calibration every (b) (4) in accordance with manufacturer recommendations. The affected sterilizer is used in the (b) (4) sterilization of medical devices, making its proper calibration and maintenance directly critical to product sterility assurance. Despite the identified lapse, your firm did not conduct an adequate assessment of the potential impact to products processed during the lapse period. Specifically, the assessment failed to identify:

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Travis Byrd, Site Operations Manager	
FIRM NAME Infinity Labs SD, Inc	STREET ADDRESS 1836 Stone Ave
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- The types and quantities of products processed through the sterilizer during the lapse period, and
- A review of associated work orders for those products.

This failure to assess product impact is inconsistent with the problem containment requirements defined in SOP-011, *Corrective and Preventative Procedure*, Revision P, Section 7.6.5, which states: *"the goal of problem containment actions is to evaluate the extent of the problem and to stop the spread of the problem as quickly as possible. Problem effects must be contained, and prompt action is important."*

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	William R Chang, Investigator X William R Chang Investigator Signed By: WILLIAM R. CHANG - S Date Signed: 06-03-2026 10:44:52	6/3/2026

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Annotations to Observations

Observation 1: Under consideration

Observation 2: Promised to correct

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."