DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 800 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	2/3/2026-2/9/2026* FEI NUMBER 1450962

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Grant R Gavrick, Vice President

FIRM NAME	STREET ADDRESS
Indilab, Inc.	10367 Franklin Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Franklin Park, IL 60131-1542	Manufacturer and Contract Manufacturer

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

Design and development of product was not adequately planned and controlled.

Specifically,

Your firm conducted a process qualification for the printing of Indilab Indistrip 4" Steam Indicator Strip (IND400S, a class II medical device) using a new (b) (4) under PQ REPORT # (b) (4) dated 10/26/2023) with a failure effect of this machine which could lead to defective material. Only (b) (4) of product was manufactured (Lot # (b) (4), manufactured in 2023) for the process qualification and this fails to demonstrate that the process will consistently produce the same results (repeatability). On 2/5/2026, I (JAV) was told that no other lots of product have been created of this brand of product since 2023 but that the (b) (4) validation lot (Lot # (b) (4) including approximately (b) (4) strips) was distributed to a customer in (b) (4) for market use.

OBSERVATION 2

The written MDR procedure does not include documentation and recordkeeping requirements for all Medical Device Reports and information submitted to FDA.

Specifically,

Your firm manufactures IndiStrip (a class II medical device with under K875193) which is a sterilization indicator for medical devices. Your current Customer Complaint Procedure (SP-14-002,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jesse A Vazquez, Investigative Engineer	X Jesse A Vazquez Investigative Engineer Signed By: JESSE A. VAZQUEZ - S Date Signed: 02-09-2026 10:56:36	2/9/2026

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Revision L) and/or Product Recall Procedure (SP-14-003, Revision D) fail to have instructions on how and when to report a potential voluntary recall of this medical device to the FDA.

For example, your current Product Recall Procedure fails to:

a) have a way to determine if a recall is reportable to the FDA;
b) have instructions on how to report it to FDA if reportable;
c) reference 21 CFR 806 as a reference document in the Section 10 (Titled, "References").

***DATES OF INSPECTION**
2/03/2026(Tue), 2/04/2026(Wed), 2/05/2026(Thu), 2/09/2026(Mon)

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Annotations to Observations

Observation 1: Promised to correct by 05/15/2026

Observation 2: Promised to correct by 05/15/2026

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	Jesse A Vazquez, Investigative Engineer X Jesse A Vazquez Investigative Engineer Signed By: JESSE A. VAZQUEZ - S Date Signed: 02-09-2026 10:56:36	2/9/2026

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."