DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
109 Holton Street Winchester, MA 01890 (781)587-7500 Fax:(781)587-7556	6/23/2025-7/2/2025*
	FEI NUMBER 3013391155

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Rita V. Jacob, Vice President Clinical Administration

FIRM NAME	STREET ADDRESS
Micro Medical Solutions, Inc.	175 New Boston St. Suite H
CITY, STATE, ZIP CODE, COUNTRY Woburn, MA 01801-6257	TYPE ESTABLISHMENT INSPECTED Sponsor

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:
The following observation relates to the conduct of the following study:
(b) (4)

OBSERVATION 1
For an investigational study, proper monitoring was not ensured.

Specifically,

The Sponsor did not properly monitor to ensure the (b) (4) images met the requirements for the (b) (4) Core Laboratory to adequately review the images per the (b) (4) Core Laboratory procedures.

A total of (b) (4) images were sent from the study sites to the (b) (4) Core Laboratory. However, 288 of the (b) (4) images taken were determined by the (b) (4) Core Laboratory to be Non- Diagnostic, for which the (b) (4) Core Lab could not make a determination if the Target Lesion was (b) (4), (b) (4) or (b) (4) .

*DATES OF INSPECTION
6/23/2025(Mon), 6/24/2025(Tue), 6/25/2025(Wed), 6/26/2025(Thu), 6/27/2025(Fri), 6/30/2025(Mon), 7/01/2025(Tue), 7/02/2025(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Matthew C Watson, Investigator	X Matthew C Watson Investigator Signed By: Matthew C. Watson -S Date Signed: 07-02-2025 15:37:25	7/2/2025

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Annotations to Observations

Observation 1: Not annotated

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Matthew C Watson, Investigator X Matthew C Watson Investigator Signed By: Matthew C. Watson -S Date Signed: 07-02-2025 15:37:25	7/2/2025

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."