DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	4/13/2026-4/16/2026
	FEI NUMBER 1527607

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Thomas W. Richards, Director of Quality

FIRM NAME	STREET ADDRESS
SRI Healthcare, Llc	7086 Industrial Row Dr
CITY, STATE, ZIP CODE, COUNTRY Mason, OH 45040-1363	TYPE ESTABLISHMENT INSPECTED 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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Requirements for infrastructure maintenance activities that can affect product quality, including the interval of performing the maintenance activities, have not been documented.

Specifically, your firm's procedure (document number 712, (b) (4) Sterilizer Checks and Maintenance, Rev 06, effective 6/13/2024) lists several action items that must be completed and documented (b) (4) However, these requirements were not fulfilled. For example:

1. Section 1.1 of your firm's procedure (b) (4) Sterilizer Checks and Maintenance, Revision 06, states, "Before starting the sterilizer, perform the required preventive maintenance (PM) task (b) (4) and cleaning tasks, and document on Form 7121, (b) (4) Sterilizer Checks and Maintenance." The following sterilizer checks on Sterilizer (b) (4) were performed without documenting the results during the following dates:

(b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Amber M Capello-Jones, Investigator	X Amber M Capello-Jones Investigator Signed By: AMBER M. CAPELLO-JONES -S Date Signed: 04-16-2026 09:28:55	4/16/2026

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2. Section 1.20 of your firm's procedure, (b) (4) Sterilizer Checks and Maintenance Revision 6, states that results of Leak tests are documented in the Sterilizer Logbook, Form 7080. The results of the Leak tests were not documented on the following dates in the 2025 Sterilizer (b) (4) logbook:

(b) (4)

OBSERVATION 2

Top management did not review the quality management system at documented planned intervals to ensure its continued suitability, adequacy, and effectiveness.

Your firm's procedure—document 1, Quality Manual, Rev 02, effective 9/11/2018, Section 2.0, Management Review—requires that "The management review is held at least (b) (4) at the corporate level and at least (b) (4) at the facility level to conduct systematic reviews of the QSEs." However, in 2024, your firm failed to conduct the required (b) (4) management review meetings at the facility level as specified.

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Annotations to Observations

Observation 1: Promised to correct

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."