DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	3/9/2026-3/11/2026
	FEI NUMBER 3010067148

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kipling J. Glass, Chief Operating Officer

FIRM NAME	STREET ADDRESS
Seriously Clean, Ltd.	1075 W Kathryn St Ste 6
CITY, STATE, ZIP CODE, COUNTRY Nixa, MO 65714-7949	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

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

Specifically,

Your firm utilizes (b) (4) scales for production of Unclassified, K113693, Nixall Wound and Skin Solution. The scales measure the fill weight, a critical specification, for the finished product. None of the scales have been calibrated. Approximately (b) (4) units of the Nixall solution were manufactured in 2025.

OBSERVATION 2

The labels of the medical device(s) do not bear a unique device identifier (UDI) that meet the requirements of 801 Subpart B and 21 CFR 830.

Specifically,

Your Unclassified, K113693, Nixall Wound and Skin Solution product labels do not have unique device identifiers. (b) (4) units of the Nixall solution were manufactured in 2025.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Eric C Fox, Investigator	X Eric C Fox Investigator Signed By: 2001885254 Date Signed: 03-11-2026 10:16:28	3/11/2026

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OBSERVATION 3

Records of the results of evaluation of supplier capability or performance were not adequately maintained.

Specifically,

A. Your Supplier Evaluation & Monitoring SOP, QP 705, Rev. 1, 08/30/2022, states that suppliers should have an initial supplier evaluation, a risk-based assessment, and periodic re-evaluation (b) (4) or (b) (4) . Suppliers (b) (4) and (b) (4) provide labels and water, respectively, for production of the Unclassified, K113693, Nixall Wound and Skin Solution. Neither supplier has a documented initial supplier evaluation or a risk-based assessment.

B. Your Supplier Evaluation & Monitoring SOP, QP 705, Rev. 1, 08/30/2022, states that a (b) (4) (b) (4) is an organization that supplies a key, raw material or component, the failure of which to meet specified requirements could cause a significant degradation in the safety and performance of the device(s). (b) (4) provides the water which is the primary component in the Unclassified, K113693, Nixall Wound and Skin Solution. (b) (4) is classified as a "Low" risk category supplier.

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: 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."