DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	12/1/2025-12/5/2025
	FEI NUMBER 3024999439

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Courtney D. Cormier, Quality Assurance Manager

FIRM NAME	STREET ADDRESS
Safesource Direct Glove Plant	142 Lake Talon Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Broussard, LA 70518	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

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically, your procedure SOP-008 – Feedback and Complaint Handling, Version 3, Effective Date: 08/02/2024, has not been adequately implemented. For instance:

Your firm's complaint handling process does not ensure that customer complaints are evaluated in a uniform and timely manner for the requirements of medical device reportability and for the need or justification for investigation or no investigation.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Monica C Burgos Garcia, Investigator

X Monica C Burgos Garcia
Investigator
Signed By: Monica C. Burgos-garcia -S
Date Signed: 12-05-2025 15:31:24

DATE ISSUED

12/5/2025

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Annotations to Observations

Observation 1:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Monica C Burgos Garcia, Investigator X Monica C Burgos Garcia Investigator Signed By: Monica C. Burgos-garcia -S Date Signed: 12-05-2025 15:31:24	12/5/2025

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."