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	3/17/2026-3/23/2026* FEI NUMBER 3010140265

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Heather V. Nigro, SVP Regulatory, Quality, and Clinical Affairs

FIRM NAME	STREET ADDRESS
CSA Medical, Inc.	131 Hartwell Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Lexington, MA 02421-3105	Specification Developer

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 WE OBSERVED:

OBSERVATION 1

Procedures to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation, and disposition of nonconforming product were not adequately documented.

Specifically, your nonconforming files have not been adequately maintained in accordance with procedure *09-00029-07 and 09-00029-08: Nonconformance Process (Effective Date: November 9, 2021 and March 14, 2026)*. The following deficiencies were identified during the review of seven nonconforming files:

- Five of seven files did not contain documented justification for corrective action decisions.
- Two of seven files did not contain documented determination regarding whether corrective action or supplier corrective action was required.
- Seven of seven files did not contain documented evidence of nonconforming trending.

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*DATES OF INSPECTION

3/17/2026(Tue), 3/18/2026(Wed), 3/19/2026(Thu), 3/23/2026(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Nabil Nakhoul, Investigator Thomas Siebertz, Investigator X Nabil Nakhoul Investigator Signed By: 2001920799 Date Signed: 03-23-2026 13:32:44	3/23/2026

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Annotations to Observations

Observation 1: Not annotated

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	Nabil Nakhoul, Investigator Thomas Siebertz, Investigator X Nabil Nakhoul Investigator Signed By: 2001920799 Date Signed: 03-23-2026 13:32:44	3/23/2026

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."