DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	2/9/2026-2/11/2026 FEI NUMBER 1038185

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Natasha Y. Clay, Quality Manager

FIRM NAME	STREET ADDRESS
Coeur Inc.	209 Creekside Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Washington, NC 27889-9094	Contract 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.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Information gathered in the feedback process does not serve as potential input into risk management for monitoring and maintaining product requirements as well as the product realization or improvement processes.

Specifically, your firm failed to assess risks to patients and users when syringes break or burst. Between September 2024 and January 2026, your customer received (b) (4) complaints regarding syringes breaking or bursting. On October 1, 2024, your firm opened CAPA, CQFI-75-2024-732, in response to your customer reporting multiple instances of CT syringes breaking in the field.

According to your Risk Management Procedure (Rev. 01, Control #00-2-010, Effective Date: 7/2/2024), Section 3.4.1 states that sources of information used to identify risks include the firm's in-process and post-production information from customer complaints and feedback. Additionally, Section 3.5.3 of the same procedure states that the pFMEA will address risks associated with the process, downstream processes, production function, or use.

The pFMEA dated 6/9/2025 did not assess the complaints and feedback concerning syringe breakage and its effect on patients or users, despite the ongoing receipt of these (b) (4) complaints. Your firm's failure to use this complaint information left unidentified risks to patient and user safety related to syringe breakage.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Lashawn M Elam, Investigator X Lashawn M Elam Investigator Signed By: Lashawn M. Elam -S Date Signed: 02-11-2026 16:26:38	2/11/2026

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OBSERVATION 2

Outsourced processes that affect product conformity to requirements were not adequately monitored and controlled.

Specifically, your firm failed to conduct an on-site audit of a critical sterilization supplier as required by your procedure. This sterilizer is responsible for sterilization of syringes and accessories which are Class II Medical Devices used to administer contrast media into the human vascular system. This supplier is designated as a critical supplier per your Approved Supplier list (Rev. 03, Control 75-3-001). According to your procedure Supplier Evaluation and Approval (Rev. 03, Control #00-74-2-002, Section 2.1.2), on-site audits are required (b) (4) for critical suppliers. An on-site audit was conducted on 2/2/24, but no audit was conducted in 2025. A desk audit performed on 2/9/2026 does not fulfill the (b) (4) on-site audit requirement for 2025.

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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."