DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301)594-4695 Fax:(301)594-4715	3/2/2026-3/5/2026
	FEI NUMBER 3015924373

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mehaboob Ali, Head of Quality

FIRM NAME	STREET ADDRESS
AUSA MEDICAL DEVICES PVT LTD	Plot No 15b Bommasandra Industrial Area, Anekal Taluk
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Bengaluru, Karnataka, 560099 India	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

Corrective action was not adequately taken to eliminate the cause of nonconformities in order to prevent recurrence.

Specifically,

During review of the corrective and preventive action (CAPA) system, CAPAs associated with the recurring nonconformance of cutter tip damage observed during assembly of the [redacted] were evaluated. Five CAPAs were requested for this issue. Review of closed CAPAs dated 01/24, 07/15, 08/11, and 10/13 showed that the corrective action implemented was not effective. Furthermore, the same nonconformance continues to be observed during manufacturing.

OBSERVATION 2

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

Specifically,

Your process Failure Mode and Effects Analysis (pFMEA) for the [redacted] is

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Esteban Beltran, Investigator	X Esteban Beltran Investigator Signed By: ESTEBAN BELTRAN - S Date Signed: 03-05-2026 01:16:57	3/5/2026

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(b)(4). During review of the process Failure Mode and Effects Analysis (pFMEA) for the assembly process, the failure mode "cutter tip damage" was identified with an occurrence ranking of - ("slight") or - ("low") depending on the manufacturing step.

According to the organization's defined occurrence ranking criteria:
- Occurrence 4 corresponds to a failure rate of (b)(4)
- Occurrence 5 corresponds to (b)(4)

Manufacturing data reviewed indicated an observed occurrence rate of (b)(4) for cutter tip damage.

Based on the organization's defined occurrence criteria, a failure rate between (b)(4) corresponds to an occurrence ranking of - ("very high"). Therefore, the observed occurrence rate corresponds to an occurrence level significantly higher than the ranking currently documented in the pFMEA.

OBSERVATION 3

Documents required by the quality management system have not been adequately controlled.

Specifically,

The organization could not demonstrate that records used to track raw material quantities and storage locations are maintained accurately and in a controlled manner.

Material quantities were maintained in an Excel spreadsheet, while storage locations and quantities were documented on paper records posted in the storage area and on storage shelves. These records were not controlled and there was no method demonstrated to ensure consistency between them.

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Under consideration

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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."