DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	2/9/2026-2/13/2026* FEI NUMBER 1526611

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michael R. Fillion, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Command Medical Products LLC	15 Signal Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ormond Beach, FL 32174-2984	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

Product was not identified by suitable means throughout product realization.

Specifically, on February 9, 2026 during the facility walkthrough, an unlabeled bag containing (b) (4) product and (b) (4) was observed pinned to a (b) (4) in the (b) (4) room. The bag had no label, lot number, product identification, or status marking. Management was unable to identify what the bag was for.

On February 10, 2026, management identified the unidentified parts as (b) (4) that were leftover samples. During follow up questioning, the Quality Assurance Manager stated:

a)Lot number: "Of course it wasn't identified so we don't have any of that"

b)Status (conforming/nonconforming): "Don't know"

c)Duration in location: "Can't say for sure how long the (b) (4) were there"

d)Nonconformance record: "We don't know"

Your firm's procedure PR-QA047 Handling, Storage, Packing, Preservation, Delivery, Customer Property Rev E (dated 06-14-2024), Section 7.0 Storage, Part E states: (b) (4)

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Brandon P Thompson, Investigator X Brandon P Thompson Investigator Signed By: Brandon P. Thompson -S Date Signed: 02-13-2026 12:12:38	2/13/2026

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(b) (4) The unlabeled product did not meet this requirement.

Product must be identified throughout product (b) (4) to prevent mix-ups, ensure traceability, control product status, and prevent unintended use. Unidentified product in manufacturing areas poses risk of mix-up with conforming product and potential unintended use.

OBSERVATION 2

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

Specifically, on February 9, 2026, (b) (4) were observed in the (b) (4) (b) (4) room used for manufacturing medical device part number (b) (4). The (b) (4) contain (b) (4)
The (b) (4) are referenced in Manufacturing Procedure MP 00.416 Rev C., dated 10-03-2023, Section 4 "Build (b) (4) "

The (b) (4) are not controlled as documents:

a) There is no revision level identified on either (b) (4) The Senior Quality Engineer and Quality Assurance Manager both confirmed no revision level visible on the (b) (4) on February 10, 2026

b) They are not listed as controlled documents. MP 00.416 Section 4 lists (b) (4) as (b) (4) not as controlled documents.

c) They are not addressed in the document control procedure

d) They did not follow firm's procedure EP 00.107 Tooling Introduction and Control Rev: Original, dated 12-08-16, for manufacturing aids. The Quality Assurance Manager stated it should have went through this procedure.

Without revision identification and document control, there is no assurance (b) (4) will be

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updated when assembly procedures or components change.

***DATES OF INSPECTION**

2/09/2026(Mon), 2/10/2026(Tue), 2/11/2026(Wed), 2/13/2026(Fri)

AMENDMENT 1

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Annotations to Observations

Observation 1: Promised to correct by 04/30/2026

Observation 2: Promised to correct by 04/30/2026

AMENDMENT 1

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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."