DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139	5/5/2026-5/12/2026* FEI NUMBER 1825560

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michael W. Czop, President and CEO

FIRM NAME	STREET ADDRESS
Domico Med-Device Llc	14241 N Fenton Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fenton, MI 48430-1541	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

One or more processes for risk management in product realization have not been adequately documented.

Specifically,

The following identifies gaps in your firm's risk management procedure (SOP-003-0001, Rev. "~~04~~ **04.1**, ED: 09APR2026) that undermine the objectivity, consistency, and verifiability of Detection and Severity scoring in the process Failure Mode and Effects Analysis (pFMEA), as evidenced in Risk File RF-0001 (Patient Positioning – FOAM, REV 04, dated 26-Mar-2024).

- Your firm's risk management procedure (SOP-003-0001, Rev. 04.1) defines Detection scores as follows: a score of (b)(4) corresponds to detection by an operator through (b) (4) means, capturing (b) (4) of failures; a score of (b)(4) corresponds to detection using (b) (4) ; and a score of (b)(4) requires (b) (4) performed at defined intervals. The procedure does not include any language permitting the combination, or "stacking," of multiple visual inspections as a basis for assigning a lower Detection score.

  Despite this, RF-0001 (Patient Positioning – FOAM, REV 04, dated 26-Mar-2024) contains

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instances where Detection scores of "~~3 or 2~~ **4 or 3**" are assigned to controls consisting solely of visual inspections. For example:

- The failure mode "Damaged Blade / Dull Blade" (Potential Failure Effect: Poor Quality Cuts (Visual)) lists a Current Control of "Inspection Operator Visual" and is assigned a Detection score of (b)(4) both before and after actions taken. This entry is internally consistent with the procedure's scoring criteria.
- The failure mode "Damaged Blade / Dull Blade" (Potential Failure Effect: Poor Quality Cuts) lists two Current Controls — "Receiving Inspection (Visual)" and "In-Process Inspection (Visual)" — both of which are visual in nature, yet is assigned a Detection score of (b)(4) which the procedure reserves for (b) (4) detection methods.

The procedure does not define a methodology by which combining multiple visual inspections qualifies for a Detection score of (b)(4) rather than (b)(4) Evidence of inconsistent application was observed across the pFMEA entries. This practice resulted in a lower RPN. For example, the failure mode "Break a Blade" (Potential Cause: Improper Maintenance or Set-Up) carries a Severity of (b)(4) and an Occurrence of (b)(4) A Detection score of (b)(4) — consistent with the procedure's definition of visual inspection — would yield an RPN of 32, exceeding the firm's acceptability threshold of (b)(4). However, the assigned Detection score of (b)(4) yields an RPN of 24, placing the failure mode (b) (4) .

☐ Your firm's risk management procedure establishes a severity rating scale in which a score of (b)(4) is defined as "(b) (4)" and a score of (b) (4) is defined as "(b) (4)" This distinction is actively applied in completed risk assessments. For example, RF-0001 (Patient Positioning – FOAM, REV 04, dated 26-Mar-2024) assigns a Severity of (b)(4) to "Nonconformance (Material) Primary" and a Severity of (b)(4) to "Nonconformance (Material) Secondary" for the same failure mode ("Wrong (b)(4)"), demonstrating that the (b) (4) function distinction is used to differentiate severity scores. However, your firm has not established — in its risk management documentation, design transfer documentation, or any other controlled document — a definition of what constitutes the primary intended function versus the secondary intended function of the (b) (4) – (b) (4) device,

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or of any other device subject to this scoring framework. Without documented definitions, the basis for assigning Severity scores of (b)(4) versus (b)(4) cannot be objectively determined, consistently applied across risk assessments, or verified by internal or external reviewers.

OBSERVATION 2

Your firm did not adequately determine the monitoring and measurement to be undertaken and the related equipment needed to provide evidence of conformity of product to requirements.

Specifically,

Per *Establishing and Maintaining Equipment Files* (WI-003-0019, Rev. 04, ED: 22APR2026), results of the review and justifications for increased calibration/maintenance intervals are required to be documented in the Equipment File. During review, it was found that this requirement is not being followed — results of the review and justifications for increased intervals are not being documented in the Equipment File as specified.

I reviewed a memo (Dated: "~~24JUL2020~~ **24April2026**) that identified (b)(4) pieces of equipment with increased calibration intervals; however, the Director of Quality said none of the corresponding Equipment Files contained documented justification for these increases, as required by WI-003-0019.

OBSERVATION 3

Procedures for timely complaint handling do not adequately include requirements and responsibilities for receiving and recording information and investigating complaints.

Specifically,

A review of the complaint handling system identified gaps in investigation documentation and inter-site responsibility assignments, as follows:

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- The procedure *Feedback and Complaint Handling* (SOP-003-0015, Rev. 07 ED: 03NOV2025) (Section 3.2.6) requires that the results of complaint reviews, evaluations, and any actions taken be documented on F-003-0013 *Complaint Evaluation and Investigation*, interviews conducted as part of complaint investigations were not documented in the complaint files reviewed. Specifically, the complaint files lacked documentation of the individuals interviewed and the topics discussed during those interviews.

- The complaint handling for the Mexico manufacturing site is performed by personnel located at the Fenton facility. No quality agreement, procedure, or other documented arrangement has been established to define which entity is responsible for receiving, evaluating, investigating, and reporting complaints, or to delineate the responsibilities between the two sites.

OBSERVATION 4

Production controls do not include qualification of infrastructure.

Specifically,

During the inspection, your firm was asked to produce documentation demonstrating that Installation Qualification (IQ) and Operational Qualification (OQ) had been performed for Oven - Asset #91, 5 Axis Router - Asset #192, Cutting Table - Asset #295, and Sewing Machine - Asset #1015, as required for the design transfer of a Class II, Special Controls Device [(b) (4)]. Your firm was unable to produce such records.

When asked, the Director of Quality stated that IQ/OQ was not performed because the design transfer product "utilizes existing equipment and processes." Your firm referenced its procedure for the validation of legacy equipment and processes, *Master Validation Plan* (MVP-0001, Revision: 00, ED: 14-FEB-2020) which states that such equipment and processes may be considered qualified based on a

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risk-based assessment indicating that they are used in the manufacture of (b) (4), have (b) (4), and have generated (b) (4) over the lifespan of the legacy products.

No IQ/OQ records were produced for these assets, and no documented risk-based assessment was provided to support the legacy qualification determination.

OBSERVATION 5

Corrective action procedures defining the requirements for determining the causes of nonconformities, planning and documenting action needed and implementing such action, verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device and reviewing the effectiveness of corrective action taken have not been adequately documented.

Specifically,

During the CAPA system review, observations were identified related to inadequate root cause investigation methodology, missing risk assessments for supplier corrective action requests, and the absence of a tracking mechanism for supplier nonconformances.

a) Inadequate Root Cause Investigation – Your firm's procedure *Corrective Action & Preventive Action* (SOP-003-0017, Rev. 05.1, ED: 14JUL2022) states that the user may use structured problem-solving methodologies (e.g., (b) (4)). However, a review of CAPA 2023-12, CAPA 2025-12, and CAPA 2026-03 found that structured problem-solving methodologies were not utilized., and that the root cause states that it was based off of some interviews being completed, however who and what was interviewed was not detailed.

b) Your firm allows received Supplier Corrective Action Requests (SCARs) to be documented on the

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customer's SCARs documentation. However, your firm did not document whether a risk assessment was required since you are utilizing your customer's documentation. Per your CAPA procedure, a risk assessment must be performed and documented, and the assessment will be verified at closure. I reviewed one SCAR record linked to CAPA 2023-12, and there was not a risk assessment documented.

c)During review of your *Supplier Corrective Action Request* procedure (SOP-009-0004, Rev. 00), it was observed that your firm has no established system or mechanism to detect, track, or record instances in which

☐A supplier fails to include proper documentation and/or a Certificate of Conformance
☐A supplier ships an incorrect quantity of parts

Without the ability to capture and monitor these occurrences, your firm cannot reliably evaluate whether a Supplier Corrective Action Request (SCAR) is warranted, as required in section 3.1 of the procedure.

OBSERVATION 6

Records of complaint investigations do not include any unique device identifier (UDI) or universal product code (UPC) and any other device identification(s).

Specifically,

Your firm's complaint handling procedure, *Feedback and Complaint Handling* (SOP-003-0015 , Rev. 07, effective 03NOV2025), does not include a requirement to document the Unique Device Identifier (UDI) in the complaint file. Consistent with this gap in the procedure, UDI was not documented in the complaint records reviewed.

***DATES OF INSPECTION**

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5/05/2026(Tue), 5/06/2026(Wed), 5/07/2026(Thu), 5/08/2026(Fri), 5/11/2026(Mon), 5/12/2026(Tue)

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Annotations to Observations

Observation 1: Not annotated

Observation 2: Not annotated

Observation 3: Not annotated

Observation 4: Not annotated

Observation 5: Not annotated

Observation 6: Not annotated

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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."