DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 800 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	6/16/2026-6/24/2026* FEI NUMBER 1000036860

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Douglas V. Johnson, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Douglas Medical Products, Inc.	361 Banbury Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Mundelein, IL 60060-1108	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

A risk-based approach to the control of the appropriate processes needed for the quality management system has not been adequately applied.

Specifically, your firm is a specification developer for class II (b) (4) (b) (4) (b) (4)) and (b) (4) (b) (4)) which are intended to be used to administer (b) (4) to patients. Your firm has distributed (b) (4) units from June 2022 through June 2026. Your firm has failed to adequately ensure a risk-based approach to the control of appropriate processes needed for the quality management system, including the failure to adequately document and maintain risk management documentation to ensure that risks associated with those processes are controlled. Your firm has not documented or maintained a risk management plan and has an incomplete hazard analysis documented for all failure modes documented in your DFMEA. For example, your firm did not address risk for particulate matter and did not update your risk management documentation to include particulate matter after the receipt of 19 complaints regarding issues of particulate matter within the (b) (4) and (b) (4) .

OBSERVATION 2

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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Shuana H Xiong, Investigator Natasha R Johnson, Investigator	X Shuana H Xiong Investigator Signed By: Shuana H. Xiong -S Date Signed: 06-24-2026 10:54:04	6/24/2026

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Specifically, your firm is a specification developer for class II (b) (4) (b) (4), (b) (4)) and (b) (4) (b) (4)) which are intended to be used to administer(b) (4) to a patient. Your firm failed to follow your CAPA procedure, QA-037 (Rev. C, 01/16/2022) and implement a corrective action to eliminate the cause of nonconformities. For example, between May 2022 and June 2026, your firm received 19 complaints regarding particulate matter identified within Class 2 (b) (4) and (b) (4) . According to your quality manager your firm did not initiate a CAPA to address the trend of particulate matter complaints because the source of the particulate matter was determined to be different for each complaint. However, Customer Complaint records 66, 67, and 68, which represents a trend per Trend Analysis Procedure (QA-020, Rev. IR, 10/01/2016), documents particulate matter due to user error and your firm did not open a corrective action.

OBSERVATION 3

Procedures to control design and development changes were not adequately documented.

Specifically, your firm is a specification developer for class II (b) (4) (b) (4) (b) (4) and (b) (4) ((b) (4)) which are intended to be used to administer(b) (4) to patients. Your firm failed to adequately follow the design change processes established in your Design Control Procedure (QA-038, Revision IR, 10/01/2016). Your firm completed a design change (ECO001) to change the medication site (b) (4). This change of material was completed in response to complaints of particulate matter within the finished medical devices. Your firm completed another design change (ECO002) to remove the (b) (4) , which was completed in response to particulates sourced from the (b) (4) . Your firm failed to adequately verify the effects of these design changes prior to implementation as described in QA-038 section 14.0.

OBSERVATION 4

Records of the results of evaluation, selection, monitoring and re-evaluation of supplier capability or performance and any arising necessary actions were not maintained.

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Specifically, your firm is a specification developer for class II (b) (4) (b) (4) (b) (4)) and (b) (4) ((b) (4)) which are intended to be used to administer (b) (4) to patients. Your firm has distributed (b) (4) units from January 2022 to June 2026. Your firm has failed to adequately monitor and perform a vendor evaluation for a level (b) (4) risk vendor as required by your Vendor Performance Review procedure (PU-009, Rev. IR, 10/01/2016). For example, PU-0009 requires level (b) (4) risk vendors to be evaluated based on product quality measurements, documentation, file review, service and responsiveness. Your firm documented on FORM 5159 a reference to the contract manufacturer's self-audit in replacement of the evaluation review, however, PU-009 does not specify that the use of a self-audit is equivalent to a vendor evaluation review.

***DATES OF INSPECTION**

6/16/2026(Tue), 6/17/2026(Wed), 6/22/2026(Mon), 6/24/2026(Wed)

X Natasha R Johnson
Investigator
Signed By: Natasha R. Johnson -S
Date Signed: 06-24-2026 10:54:39

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

Observation 4: 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."