

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303) 236-3000 Fax: (303) 236-3100		DATE(S) OF INSPECTION 1/6/2025-1/9/2025 FEI NUMBER 3011853315	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Brent A. Yourgliche, Center Manager			
FIRM NAME Biomat USA, Inc.		STREET ADDRESS 1188 South Sage Drive	
CITY, STATE, ZIP CODE, COUNTRY Cedar City, UT 84720		TYPE ESTABLISHMENT INSPECTED Source Plasma Firm	
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 Failure of equipment to perform in the manner for which it was designed so as to assure compliance with the official requirements prescribed in 21 CFR 606. Specifically, while qualifying your firm's new plasmapheresis machines, your firm did not document either an investigation into the reason for failure nor if the machines were repaired prior to being signed off and placed into use for the following plasmapheresis machines:			
Machine (b) (4) 08/16/2022: Initial evaluation completed by center employee. 08/26/2022: Failed by QU due to anticoagulant being out of range. 08/27/2022: Second evaluation completed by center employee. 08/27/2022: Failed by QU due to anticoagulant being out of range. 08/29/2022: Third evaluation completed by center employee. 09/06/2022: Failed by QU due to unsuccessful donation. 09/01/2022: Fourth evaluation completed by center employee. 09/01/2022: QU signed off machine as suitable for use.			
Machine (b) (4) 08/16/2022: Initial evaluation completed by center employee. 08/18/2022: Failed by QU due to under draw. 08/16/2022: Second evaluation completed by center employee.			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Emily B Camire, Investigator		DATE ISSUED 1/9/2025 Emily B Camire Invsr Ignator Signed By: EMILY B. CAMIRE -G Date Signed: 01-09-2025 11:37:38 _____ X

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08/18/2022: Failed by QU due to not enough saline. 08/16/2022: Third evaluation completed by center employee. 08/18/2022: Failed by QU due to anticoagulant being out of range. 08/16/2022: Fourth evaluation completed by center employee. 08/18/2022: QU signed off machine as suitable for use. Since 2022, your firm has collected approximately (b) (4) liters of source plasma.			
OBSERVATION 2 Failure to perform a thorough investigation of an unexplained discrepancy and a failure of a lot or unit to meet any of its specifications. Specifically, your firm failed to completely document the investigation performed related to the following deviations: - Deviation #2499731 states that "on 09/24/24 there was an overdraw due to machine malfunction, (b) (4)." The machine was taken out of service on 09/24/2024 and placed back into service on 10/01/2024. The deviation fails to include enough information to support the root cause as a machine malfunction. - Deviations (BPDR) #2347066, #2329710, and #2329707 involve (b) (4) units of source plasma that were distribute to consignees and (b) (4) units of source plasma that remained in-house. The center failed to reclassify the (b) (4) units for destruction due to lack of testing. Documentation related to the investigation on how the deviation was discovered was not included in any of the deviation reports.			
OBSERVATION 3 Records are not concurrently maintained with the performance of each significant step in the collection of each unit of blood and blood components so that all steps can be clearly traced.			
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Specifically, your firm does not document in the machine's electronic instrument log all alerts, alarms or error messages that require troubleshooting the plasmapheresis machine. Your firm also does not keep documentation of what was done to address the alert, alarm, or error message if a machine does not need to be immediately taken out of service. For example, on 01/06/2025, a phlebotomist was observed setting up machine (b) (4) with a plasmapheresis (b) (4). While setting up the machine, alert with (b) (4) presented on the machine. The phlebotomist explained that the alert was due to low pressure. The phlebotomist opened a (b) (4) to set up the machine and the alert occurred again. The phlebotomist moved the donor to a new machine. Documentation of the alert and what was done to address it was not documented in the machine's electronic instrument log.			
OBSERVATION 4 Written standard operating procedures including all steps to be followed in the collection of blood and blood components for further manufacturing purposes were not always established. Specifically, your firm has not established a procedure that provides instruction in the event that a plasmapheresis machine fails your "Plasmapheresis Machine Evaluation" document (b) (4)-0021.			
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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."