DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	2/10/2025-2/13/2025
	FEI NUMBER 3014576101

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Alexander Weir, Center Manager

FIRM NAME	STREET ADDRESS
Biomat USA, Inc.	1587 Lehigh St
CITY, STATE, ZIP CODE, COUNTRY Allentown, PA 18103-3813	TYPE ESTABLISHMENT INSPECTED Source Plasma Donor Center

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
The phlebotomy site is not prepared by a method that gives maximum assurance of a sterile container of blood.

Specifically,

On 02/10/2025, phlebotomist [redacted] was observed palpating a prepared venipuncture site twice without re-scrubbing the site with a povidone-iodine swab on Applicant Donor [redacted] in the collection of source plasma unit [redacted].

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Michele Gottshall, Investigator
Matthew J Gretkierewicz, Investigator

X Michele Gottshall Investigator Signed By: Michele Gottshall -S Date Signed: 02-13-2025 09:15:57

DATE ISSUED
2/13/2025

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."