DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	2/25/2025-2/27/2025
	FEI NUMBER 3015045325

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Thomas R. Mullen, VP Operations & Product Development

FIRM NAME	STREET ADDRESS
SeaStar Medical, Inc.	3513 Brighton Blvd., Suite 410
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Denver, CO 80216-3805	Medical Device 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.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

A process whose results cannot be fully verified by subsequent inspection and test has not been validated according to established procedures.

Specifically,

Your firm has not performed the process validation - Performance Qualification (PQ) for the Quelimmune Selective Cytopheretic Device for Pediatrics (SCD-PED) Clinical Kits which consists of a SCD-PED Cartridge and SCD Blood Tubing Set according to TP-08-005 Process Validation Protocol: Performance Qualification - Production Line, SCD-PED Clinical Kits approved/signed on 01/28/2025.

X Marc A Jackson
Investigator
Signed By: Marc A. Jackson -S
Date Signed: 02-27-2025 12:35:51

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Celeta S Coves, Investigator Marc A Jackson, Investigator	X Celeta S Coves Investigator Signed By: Celeta S. Coves -S Date Signed: 02-27-2025 12:35:13	2/27/2025

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Annotations to Observations

Observation 1: Promised to correct

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Celeta S Coves, Investigator Marc A Jackson, Investigator	X Celeta S Coves Investigator Signed By: Celeta S. Coves -S Date Signed: 02-27-2025 12:35:13	2/27/2025

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."