DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900	6/11/2026-6/17/2026*
	FEI NUMBER 3013115071

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dane Kmetz, General Manager

FIRM NAME	STREET ADDRESS
ClorDiSys Solutions, Inc.	50 Tannery Rd Ste 1
CITY, STATE, ZIP CODE, COUNTRY Branchburg, NJ 08876-6034	TYPE ESTABLISHMENT INSPECTED 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 I OBSERVED:

OBSERVATION 1

There is a lack of written procedures assigning responsibility, providing cleaning schedules and describing in sufficient detail the methods, equipment and materials to be used for sanitation.

Specifically,
There is no written cleaning and sanitation procedure for the room used to load, unload and operate the sterilizer used to process the container closure system for (b) (4) (b) (4) (b) (4), lot# (b) (4) Expiry (b) (4)

***DATES OF INSPECTION**
6/11/2026(Thu), 6/12/2026(Fri), 6/15/2026(Mon), 6/17/2026(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Frederick Razzaghi, Investigator X Frederick Razzaghi Investigator Signed By: Frederick Razzaghi -S Date Signed: 06-17-2026 12:01:28	6/17/2026

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."