DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301)594-4695 Fax:(301)594-4715	2/23/2026-2/26/2026
	FEI NUMBER 3002806470

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mirko (NMN) Piccinini, Plant Manager

FIRM NAME	STREET ADDRESS
Steris S.p.A.	Via Ca' Bertoncina 29
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Seriate, Bergamo, 24068 Italy	Manufacturer (Contract sterilizer)

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

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's current Process Failure Mode Effects Analysis (pFMEA), Rev 19, dated 11/14/2025, identifies dosimeter conditioning as a hazard (Item 9), however, the risks associated with the wait-time between dosimeter irradiation during product processing and post-irradiation conditioning are not evaluated or assessed. As a result, an adequately specified post irradiation wait-time has not been established. Q08-WI-002933, [redacted] Routine Dosimetry Use, Rev 7, effective date 8/6/2024, states in paragraph 3.1.1 that the *time between end of the irradiation and beginning of incubation time should be similar as during the calibration exercise*, however, your firm's current calibration documentation, Dosimetry System Calibration Verification Report, document #02_2025, dated 7/14/2025, does not record the wait-time. Paragraph 3.1.2 of Q08-WI-002933, [redacted] Routine Dosimetry Use, states that waiting *30min and less than 720min* to initiate incubation improves the dosimeter response. Furthermore, a technical report published by your firm's dosimeter supplier, Post-Irradiation Heat Treatment of [redacted] Dosimeter Products - Technical Report, version 1, dated 2/23/2026, states in paragraph 4.4 that the time interval (wait-time) can contribute to dosimeter measurement variance and that for facilities using electron beam devices, the optimal wait time is at least one-hour post-irradiation.

Additionally, your firm's pFMEA does not evaluate or assess the risk posed by dosimeter manufacturing defects, nor the effectiveness of the current dosimeter receiving inspection control measures implemented by Q04-WI-001140, B3 Dosimeter Incoming Inspection, Rev 4, effective 5/1/2025.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Scott D Stevens, Investigator	X Scott D Stevens Investigator Signed By: 2004135571 Date Signed: 02-26-2026 05:24:49	2/26/2026

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Scott D Stevens, Investigator

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Investigator
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CITY, STATE, ZIP CODE, COUNTRY Seriate, Bergamo, 24068 Italy	TYPE ESTABLISHMENT INSPECTED Manufacturer (Contract sterilizer)

Annotations to Observations

Observation 1: 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."