

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 10903 New Hampshire Avenue Silver Spring, MD 20993 (301) 594-4695 Fax: (301) 594-4715		DATE(S) OF INSPECTION 9/22/2025-9/25/2025 FEI NUMBER 3002807091			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Steven Whelan, Quality Assurance Manager					
FIRM NAME Sterigenics UK Limited		STREET ADDRESS Cotes Park Estate			
CITY, STATE, ZIP CODE, COUNTRY Alfreton, Derbyshire, DE55 4NN United Kingdom		TYPE ESTABLISHMENT INSPECTED 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. <i>The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.</i>					
DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures. Specifically, change request CR.24.SO.027 was opened to change the nitrogen line and regulator to a PSV and reduce the nitrogen pressure from in the sterilization chambers. The Chamber 4 CR.24.SO.027, Chamber 5 Nitrogen Flow Control document, Section 6.1, Chamber 5 Nitrogen Flow, states The calculated pressure change was 47.2 mB/min. which was a failing result. No work was done to rectify the nitrogen flowrate.					
OBSERVATION 2 Corrective and preventive action activities and/or results have not been adequately documented. Specific corrective action CA-8134, opened due to customer loads impacted as a result of the temperature within the aeration room falling below the minimum temperature for more than 30 minutes. Two root causes have been identified as part of the CAPA Investigation. They are "Equipment" due to the failure of the Air Handling					
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%;"> EMPLOYEE(S) SIGNATURE Frank J Marciniak, Investigator </td> <td style="width: 40%; text-align: center; vertical-align: bottom;"> Frank J Marciniak Investigator Signed By: Frank J. Marciniak -S Date Signed: 09-25-2025 09:51:37 X </td> </tr> </table>		EMPLOYEE(S) SIGNATURE Frank J Marciniak, Investigator	Frank J Marciniak Investigator Signed By: Frank J. Marciniak -S Date Signed: 09-25-2025 09:51:37 X
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Unit to control the temperature within the Aeration Room correctly, and "Process" due to the lack of compliance in the PM Schedule for the Aeration Room. Corrective action 1 was to change the air handling unit control from pressure to temperature to ensure the air handling unit is controlling based on the temperature within the aeration room. There was no documentation showing the control was changed to temperature from pressure.			
OBSERVATION 3 Procedures for management review have not been adequately established. Specifically, the Management Review Procedure, STG-WI-1470, Section B, Facility Management Review Meeting states under 2.a, For facility/laboratory management review, facility/laboratory managers/supervisors must be present. The management review conducted 9/27/2024, covering the period from 1/1/2024 through 6/1/2024 only had four people present, the Production Manager, General Manager, EHS Manager, and Laboratory Manager. The QA Manager, Customer Service Manager, and Maintenance Managers were not present.			
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Annotations to Observations Observation 1: Observation 2: Observation 3:			
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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."