

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139		DATE(S) OF INSPECTION 1/5/2026-1/8/2026 FEI NUMBER 3008879776	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Patrick Tam, Senior Manager, Global Quality and Regulatory			
FIRM NAME J Sterling Industries, LLC		STREET ADDRESS 6825 Beatrice Dr Ste A	
CITY, STATE, ZIP CODE, COUNTRY Kalamazoo, MI 49009-7263		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.			
<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 Procedures to control environmental conditions have not been adequately established. Specifically, • Cleanroom specifications have not been adequately established. For example, • Specification for maximum surface viable or airborne viable contaminants are not adequately established. Per Bioburden Monitoring of Kalamazoo Cleanroom CR006K-WI Rev 01 08/17/2024 page 9 section 8.4.6, a limit of (b) (4) CFU is not to be exceeded. However, your firm does not have an adequate justification for the upper limit of (b) (4) CFU. Per Quality Inspection Requirements (b) (4) Product Family QIR-(b) (4) Rev D 01/07/2025 page 15, each product has a pre-sterilization bioburden alert limit of (b) (4) CFU and action limit of (b) (4) CFU. The (b) (4) product family is manufactured within the cleanroom. • Specification for minimum positive pressure has not been established in (b) (4) Controlled			
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Environmental Areas Rev 05 10/24/2025, Cleanroom Cleaning Daily Maintenance Form 1135 CRC-K Rev B 04/11/2024, or other quality records. Positive pressure monitoring is not established between the ISO 7 cleanroom and ISO 8 material air lock. - Cleanroom monitoring has not been adequately established. For example, - Monitoring of non-viable particulates was not performed in accordance with Particle Count Monitoring of Kalamazoo Cleanroom CR005K-WI Rev 01 09/13/2024. Per the procedure page 8 section 8.4.5, air samples are taken from each identified room in Appendix A at its working height, the number of locations are based on the cleanroom ISO standards with (b) (4) in the cleanroom, (b) (4) in the PAL (personnel air lock), and (b) (4) in the MAL (material airlock). However, in 5 of (b) (4) environmental monitoring records sampled (b) (4), (b) (4), (b) (4), (b) (4), and (b) (4), only the (b) (4) cleanroom locations were sampled for particle count monitoring; no samples were documented for the PAL or the MAL. - Monitoring of viable contaminants was not performed in accordance with Bioburden Monitoring of Kalamazoo Cleanroom CR006K-WI Rev 01 08/17/2024 in the following ways: - Per the procedure page 4 section 8.3.5, a (b) (4) is to be placed in one of the cleanroom and MAL locations noted in the appendix and ensure the (b) (4) are placed on working surface areas. Per the Appendix page 10, there are (b) (4) locations in the cleanroom and (b) (4) locations in the MAL. However, in 11 of (b) (4) environmental monitoring records sampled, only (b) (4) locations were sampled for viable air contaminants; the locations indicated do not					
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directly correlate with any of the established sampling locations in the appendix and are not documented to have been placed on working surface areas. - Per the procedure pages 6 – 8, sections 8.3.11-27 describe how surface viable sampling is taken but does not define sampling locations. In 11 of (b) (4) environmental monitoring records sampled, (b) (4) locations were sampled for surface viable contaminants. The sampled locations do not include work surfaces where products are assembled. Your firm does not have an established rationale for the sampling locations chosen for (b) (4) monitoring or for why (b) (4) samples are sufficient. - No viable air contaminant monitoring is required to be conducted for the personnel air lock location which is qualified as an ISO 8 cleanroom environment. In 11 of (b) (4) environmental monitoring records sampled, none contain documentation of samples taken from the personnel air lock location for either surface or air viable contaminant monitoring. Your firm does not have an established rationale for why this environment is not monitored for surface or air viable contaminants. - Investigation of environmental excursions is inadequate. Per Bioburden Monitoring of Kalamazoo Cleanroom CR006K-WI Rev 01 08/17/2024 page 9 section 8.4.6, a limit of (b) (4) CFU is not to be exceeded. Per Surface Monitoring 04/02/2025, location “(b) (4)” surface viable sampling resulted in (b) (4) CFU. Per NC IN-0171, there was no quarantine action because the (b) (4) CFU is an alert limit and does not represent a failure, based on customer inputs (b) (4) CFU is the action limit. No products were dispositioned as nonconforming. Per firm management, the (b) (4) CFU action limit is based on Finished Device Release Checklist FQA0061b Rev 7.0 10/13/2024 page 1 where the product bioburden specification per device is							
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to be less than (b) (4) CFU for the (b) (4). However, this (b) (4) CFU action limit is not adequate as an action limit for the cleanroom environment as other products manufactured in the same space, such as the (b) (4) product family, have lower CFU requirements. Per Quality Inspection Requirements (b) (4) Product Family QIR-(b) (4) Rev D 01/07/2025 page 15, each product has a pre-sterilization bioburden alert limit set to CFU and action limit (b) (4) CFU. Your firm did not adequately assess the potential product impact to the (b) (4) product family due to this environmental monitoring excursion during the investigation documented in NC IN-0171.			
OBSERVATION 2 Procedures for corrective and preventive action have not been adequately established. Specifically, Corrective and preventive actions are not initiated in accordance with established procedures. Per 13 Corrective and Preventive Actions Rev 19 08/14/2025, page 4, section 2.2, review of nonconformance records can result in a decision of corrective action required; when the nonconformance evaluation indicates a recurring or systemic issue, a new CAPA will be initiated and linked to the nonconformance. Per 12 Control of Non-conforming product Rev 27 11/07/2025 page 3 section 3.2, a risk assessment to determine the need for generating a corrective action is performed by (b) (4), then a Corrective Action is required.			
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However, in 3 of 11 customer nonconformance records reviewed (CN 140, 145, and 171), the risk assessment documented an RPN value of (b) (4) but no corrective action was initiated. - Risk assessment performed to determine CAPA initiation is inadequate. Per 12 Control of Non-conforming product Rev 27 11/07/2025 page 3 section 3.2, a multidisciplinary team, using predefined tables, shall determine the value of the nonconformity's occurrence, detection and severity. Per the occurrence table, a ranking of (b) (4) is given to nonconformances that has not previously occurred. Per vendor nonconformance NC VN-0129, on 01/03/2025, particulates and contaminants were identified on (b) (4) lot (b) (4). Per the risk assessment, the occurrence score is 1, detection score is (b) (4), and severity score is (b) (4) resulting in an RPN of (b) (4), leading to a decision of no CAPA. However, per vendor nonconformance NC VN-0090, on 06/25/2024, foreign matter or contaminants were identified on (b) (4) lot (b) (4). The same nonconformance was identified in both VN-0090 and VN-0129 for the same part and the recurrence was within 180 days. Per 12 Control of Non-conforming product Rev 27 11/07/2025 page 3 section 3.2, this is an occurrence ranking of (b) (4). If the risk assessment of NC VN-0129 was calculated using an occurrence score of (b) (4), the resulting RPN value of (b) (4) would have required the initiation of a CAPA. - Corrective and preventive action root cause investigation is inadequate. Per 13 Corrective and Preventive Actions Rev 19 08/14/2025, page 4 section 2.3, a root cause investigation will be performed which will guide the development of a CAPA plan to eliminate and prevent recurrence of the nonconformity. However, in 2 of 11 CAPAs reviewed, a root cause investigation did not adequately identify the root cause. For example:			
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- Per CA 138 on 04/01/2024 the calibration sticker for the (b) (4) torque driver was missing and master torque driver used to check drivers used in production was (b) (4) past due for calibration. Per the root cause investigation, there is no system in place for calibration or verification of torque tools. A corrective action was implemented to (b) (4) . However, the CAPA did not identify why the master torque driver was allowed to be past due for calibration; no corrections were implemented to address this deficiency. The same deficiency of past due calibrations was identified in 02/27/2025 for a multimeter and a force gauge. This deficiency was addressed via CA 147. - Per CA 152 on 04/01/2025, it was identified that screws being used during assembly were screws without (b) (4) instead of the same sized screws with (b) (4) . Per the root cause investigation, the bill of materials was incorrect and the work instructions were not available. A corrective action was implemented to correct the bill of materials, retrain the staff, and change the layout of the work area to locate (b) (4) screws where required. However, the root cause investigation did not identify cause of the incorrect bill of materials. - Verification of the effectiveness of corrective and preventive actions are not performed in accordance with established procedures. Per 13 Corrective and Preventive Actions Rev 19 08/14/2025 page 4 section 2.4, an effectiveness verification plan is determined to ensure that the precipitating issue triggering the CAPA and identified root causes have been addressed by the CAPA plan actions; specific and measurable outputs of the processes related to the originating issues shall be used to determine the pass/fail status of the effectiveness of the CAPA actions.					
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However, in 5 of 11 CAPAs reviewed (CA 138, 139, 141, 149, 152) the verification of effectiveness plan does not contain measurable outputs of the process to determine a pass/fail status for the effectiveness of the CAPA actions.			
OBSERVATION 3 Schedules for the adjustment, cleaning, and other maintenance of equipment have not been adequately established. Specifically, - The preventive maintenance for the (b) (4) equipment is not adequately established. Per Total Preventive Maintenance (b) (4) Form 1154 Rev A 08/16/2023 the sealer has (b) (4) maintenance tasks related to inspections for damage to equipment and equipment cleaning and (b) (4) maintenance tasks of inspections for damage to electrical cables and power adaptors. However, per (b) (4) Owner's Manual pages 35 – 36, maintenance activities should include (b) (4) checks for the filter /regulator system and draining of (b) (4) water and (b) (4) as well as periodic checks for tightness of screws, nuts and bolts to the sealing chamber, tools, and platens. Your firm does not have adequate rationale for why these preventive maintenance activities were not established in the preventive maintenance schedule for the equipment. - The (b) (4) equipment was not installed in accordance with manufacturer requirements. Per Installation Qualification (b) (4) Rev A 06/15/2023 page 1, the equipment is installed with electrical requirements established as (b) (4) VAC, (b) (4) Hz, (b) (4) Phase, (b) (4) Amp.			
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However, per (b) (4) Owner's Manual page 14, power requirements, the (b) (4) incoming power requirements are (b) (4) volts, (b) (4) Phase, (b) (4) Amps.			
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Annotations to Observations Observation 1: Annotation Intentionally Left Blank Observation 2: Annotation Intentionally Left Blank Observation 3: Annotation Intentionally Left Blank			
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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."