DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg71-5128 Silver Spring, MD 20993-0002 240-402-8906	8/19/2019-8/23/2019
	FEI NUMBER 3010413216

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Shinya Satomura, Managing Director

FIRM NAME	STREET ADDRESS
SIAM STERI SERVICES CO., LTD	Tambol Bankao, 700; 644 Amata Nakorn Industrial Estate
CITY, STATE, ZIP CODE, COUNTRY Phan Thong, Chon Buri, 20160 Thailand	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.

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.

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,

1. Product (b) (4) Ethylene Oxide (b) (4) sterilization using (b) (4) and sterilization (b) (4) for product (b) (4) yielded a positive BI (biological indicator) during re-validation using a (b) (4) cycle approach (b) (4) for a (b) (4) cycle exposure time on 08 Sept 2016. This cycle was originally validated and approved on 25 May 2012. (b) (4) re-validation using the same (2012 protocol) (b) (4) cycle approach for the (b) (4) cycle exposure was successfully executed and approved in (b) (4) for a total of (b) (4) sterilization batches. The cycle was increased to a (b) (4) cycle exposure time on December 8, 2016 without validation. The (b) (4) cycle validation was completed and approved on 27 Nov 2017. From the cycle failure on 08 Sept 2016 until the approved validation on 27 Nov 2017, 323 batches of product were sterilized and released without an approved process validation. (b) (4) batches (b) (4) of product (b) (4) were sterilized using the (b) (4) cycle and then re-sterilized using the (b) (4) cycle. There is no process validation for re-sterilization and no process validation using both the (b) (4) exposure time for product (b) (4).

2. (b) (4) Product: Ethylene Oxide (b) (4) sterilization using (b) (4) and sterilization

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(b) (4) for (b) (4) product (b) (4)) yielded multiple positive BIs during re-validation using a (b) (4) cycle approach (b) (4) cycle exposure time on 06 July 2018, 07 Aug 2018, 12 Aug 2018, and 23 Aug 2018. This (b) (4) cycle was originally validated and approved on 04 Mar 2013. (b) (4) re-validation using the same (2013 protocol) (b) (4) cycle approach for the (b) (4) cycle exposure was successful executed and approved in (b) (4) for a total of (b) (4) batches. The cycle was increased to a (b) (4) cycle (b) (4) cycle) on 19 Sept 2018 without validation. The (b) (4) cycle using a (b) (4) cycle approach validation was completed and approved on 21 Dec 2018. From the validation failures beginning 06 July 2018 until and the approved validation on 21 Dec 2018, (b) (4) batches of product (approximately (b) (4)) were sterilized and released without an approved, validated process.

3. Software: (b) (4) software used in ETO sterilization has not been adequately validated since it was installed and approved 31 Oct 2006. The original validation and current re-validation consist of a (b) (4) to ensure there have been no changes to the original software and that system is operational.

OBSERVATION 2

There is no documentation of the review and evaluation of a process performed in response to changes or process deviations.

Specifically,

1. There was no documented investigation for BI (biological indicator) failure during process validation/re-validation.

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a. On 08 Sept 2016, there was a BI failure during (b) (4) cycle validation of product (b) (4). There was no investigation, no alert report, no non-conformance, and no CAPA implemented. The cycle ETO exposure dwell time was (b) (4) to achieve a passing re-validation. There was no change control, evaluation, or review of the changes to the cycle.

b. 06 July 2018, there was a BI failure during (b) (4) cycle validation of (b) (4) Product. There was no investigation, no alert report, no non-conformance, and no CAPA implemented. The cycle ETO exposure dwell time was increased to achieve a passing re-validation. There was no change control, evaluation, or review of the changes to the cycle.

2. There was no documented investigation, verification, or change control for changes to a validated cycle.

On 30 Mar 2018, the customer for the validation of (b) (4) Product requested a change to the (b) (4) code from (b) (4). The customer stated the change "would not affect the current sterilization parameters". The product code change included changes to the (b) (4) After this change, the (b) (4) re-validation of the sterilization cycle on 06 July 2018 failed. The cycle exposure dwell time was increased (from (b) (4)) to achieve a passing validation on 21 Dec 2018. On 09 Feb 2019, the customer requested the (b) (4) code change from most dense (b) (4), assuring no effect to the current sterilization parameters. This product code change included changes to the (b) (4) back to the original setting (from (b) (4)). There was no investigation to verify if these changes to the (b) (4) codes affected the sterilization cycle. After the (b) (4) change, which brought the parameters back to the original settings, there was no investigation to reduce the cycle exposure dwell time from (b) (4) (back to original validated cycle).

OBSERVATION 3

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Corrective and preventive action activities and/or results have not been adequately documented.

Specifically, Non-Conformance reports are not properly maintained, investigated, documented or trended.

1. On 07 Aug 2018, ETO sterilization cycle (b) (4) was determined to be a failure due to the (b) (4) time was outside of specifications. Non-conformance report 1808008 was issued on 25 Aug 2018. There was no documented investigation and no CAPA. A sterilization certificate was issued on 17 Aug 2018 and the lot was approved and released on 22 Aug 2018.
2. On 08 Jan 2018, non-conformance report 1801003 was issued. There is no documented maintenance record maintained confirming the corrective and preventative action.
3. On 11 Dec 2017, non-conformance report 1712005 was issued for (b) (4) on finished product (b) (4). The report was closed on 12 Feb 2018 with the statement "no reoccurrence this issue within 2 months". On 30 Jan 2018, non-conformance report 1801007 was issued for (b) (4) .

OBSERVATION 4

Rework and reevaluation activities have not been documented in the device history record.

Specifically, (b) (4) containing (b) (4) of product number (b) (4) were re-sterilized and processed under a (b) (4) cycle number and (b) (4) device history record. Lot numbers and quantity of product are not recorded on the sterilization cycle record. The sterilization records for the same batches are not maintained in the same device history record.

OBSERVATION 5

Procedures for rework of nonconforming product have not been established.

Specifically, there are no procedures for rework/reprocessing or product returns. (b) (4) of product number (b) (4) originally sterilized from Sept 8, 2016 - December 6, 2016, were returned and re-sterilized using a cycle with (b) (4) the original dwell exposure time.

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

Observation 4: Promised to correct

Observation 5: 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."