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	9/25/2023-9/28/2023 FEI NUMBER 3003696170

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Torbjorn I. Skold, Chief Executive Office & President

FIRM NAME	STREET ADDRESS
Stille AB	Ekbacken 11
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Torshalla, Sodermanlands Lan [SE-04], 644 30 Sweden	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.

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

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically, I reviewed procedure title "Complaints" Doc# QA11-001R-SE, Edition 17, Dated: 09/22/2018 which specifies methods on how to receive, document, and process Complaints for your IMagiQ2 and Medstone tables. It was noted that the procedures do not adequately define on how complaint involving the possible failure of device to meet any of its specifications shall be reviewed, evaluated or investigated. I reviewed 11 complaints (Complaint C211006516, C211116576, C220104619, C220324717, C221004913, C221201998, C220815855, C2303011085, C2303011084, C2307051192, C232171075, C2305221142) and it was noted that three of the complaint (complaint# C211116576, C211006516 , C2307051192) investigation was not documented.

OBSERVATION 2

Procedures for acceptance of incoming product have not been adequately established.

Specifically, your incoming procedures titled "Ankomstkontroller och larger hantering (Arrival controls

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Kenya Destin, Investigator	X Kenya Destin Investigator Signed By: 2001724874 Date Signed: 09-28-2023 09:08:29	9/28/2023

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and warehouse management)" Doc# LOG1-002R-SE & EN, Edition 8, Dated: 10-24-2019, section 6.1 states *After carrying out the arrival check shall be appropriately documented on the deliver note [with] signature/ok for article on delivery note, number of arrivals and approvals and any number of errors, and packing slip is saved in binder.* However, when reviewing acceptance records of critical suppliers for critical components for the manufacturing of ImagiQ2 table, I noted that the packing slip failed to state the result of the acceptance activity.

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Annotations to Observations

Observation 1:

Observation 2:

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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."