DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240)402-9160 orabioinspectionalcorrespondence@fda.hhs.gov	4/17/2023-4/25/2023* FEI NUMBER 3002806457

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Georgi Jekov, Senior VP Global Operations

FIRM NAME	STREET ADDRESS
Fenwal International, Inc.	Parque Industrial Itabo Zona Franca Ind. De S.C, Carretera Sanchez Km 18 1/2 Bldgs. 48-50
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Bajos De Haina, San Cristobal, 91000 Dominican Republic (the)	Medical Device 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 WE OBSERVED:

OBSERVATION 1

Products that do not conform to specifications are not adequately controlled.

Specifically, your firm does not adequately investigate causes of product non-conformities. For example:

a. Between 29 JUNE 2022 and 17 MAR 2023, you have documented five (b) (4) kit leak non-conformances. From these, none have been investigated for root cause due to written procedure (b) (4) requiring two prior occurrences of the (b) (4) component leak non-conformance in a kit that has over (b) (4) components.

b. Between 25 JAN 2022 and 10 APR 2023, you have documented nine foreign particle non-conformances in (b) (4) kits. From these, only four have been investigated for root cause due to written procedure (b) (4) requiring two prior occurrences of the (b) (4) (b) (4) kit product code, while the same clean room is used for (b) (4) approximately (b) (4) (b) (4) kit codes.

OBSERVATION 2

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	Creighton T Tuzon, Investigator Scott T Ballard, National Expert	X Creighton T Tuzon Investigator Signed By: Creighton Tuzon -S Date Signed: 04-25-2023 13:51:19	4/25/2023

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Procedures for corrective and preventive action have not been adequately established.

Specifically, your firm does not adequately investigate the cause of process related non-conformances occurring for (b) (4) medical device kits. For example:

a. Between AUGUST 2022 and MARCH 2023, your (b) (4) water monitoring has shown increasing trends of microbial growth. There is no investigation to determine the cause of this trend.

b. Between 13 JULY and 12 AUGUST 2022, your viable surface sampling data for environmental monitoring showed increasing microbial recoveries to approximately 2X baseline levels in clean room (b) (4). This clean room is used for (b) (4) medical device kits (b) (4). There is no investigation of this trend.

c. Between OCTOBER 2022 to MARCH 2023, your firm received 3 complaints of leaking (b) (4). You have not conducted a CAPA investigation for root cause evaluation.

OBSERVATION 3

Buildings are not of suitable design to perform necessary operations.

Specifically, buildings are not adequately designed for operating (b) (4) clean rooms (b) (4) and (b) (4) where (b) (4) (b) (4) medical device kit article codes are assembled:

a. Your firm has not established or documented intended air flow or differential pressure design patterns in (b) (4) and (b) (4) where (b) (4) (b) (4) kits occurs.

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b. On 17 and 18 APR 2023, we observed air flow moving from personnel de-gowning areas into clean room for both (b) (4) and (b) (4) where (b) (4) kits occurs.

c. Throughout (b) (4) and (b) (4) quick response fire sprinkler heads (b) (4) where (b) (4) kits occurs. These sprinkler heads are not easily cleanable. Some sprinklers heads showed rough/rusting surfaces.

Since APRIL 2022, over (b) (4) units in clean room (b) (4) and (b) (4) units in clean room (b) (4) of (b) (4) medical device kits have been (b) (4) in these clean rooms on average per month.

OBSERVATION 4

Procedures to control environmental conditions have not been established.

Specifically, environmental conditions are not adequately controlled and monitored with respect to (b) (4) clean rooms (b) (4) where (b) (4) medical device article codes are assembled.

a. No limit on persons in rooms during commercial production activity.
b. No monitoring of all differential pressures applicable such as material air locks and doors.
c. No individual (b) (4) filter limits on (b) (4)
d. Non-viable particulate sampling not conducted near medical device (b) (4) products.
e. Viable surface samples are collected (b) (4) cleaning and (b) (4) batch production.
f. Viable air samples are collected (b) (4).
g. Viable surface samples are collected (b) (4).

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Since APRIL 2022, over (b) (4) units in clean room (b) (4) and (b) (4) units in clean room (b) (4) medical device kits have been (b) (4) in these clean rooms on average per month.

OBSERVATION 5

Equipment used in the manufacturing process has not been appropriately constructed to facilitate maintenance, adjustment, cleaning, and use.

Specifically, equipment surfaces showing difficult to clean and degrading surfaces were observed.

a. On 17 APR 2023, (b) (4) showed (b) (4) that move and directly contact (b) (4) showed rough and flaking surfaces as well as (b) (4) in contact (b) (4) with small crevices and adhesive surfaces exposed. These (b) (4) are used in (b) (4) kits.

b. On 18 APR 2023, (b) (4) showed (b) (4) with visible black unknown adhered residue and particulate white in color within the equipment enclosure within twelve inches of (b) (4) components used for (b) (4) (b) (4) medical device kits.

c. On 17 MAR 2023, we observed damaged (b) (4) showing emanations of fiber from the (b) (4) that moves (b) (4) through the machine.

OBSERVATION 6

Procedures to ensure equipment is routinely maintained have not been adequately established.

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Specifically, equipment and process used are not adequately documented. For example:

a. (b) (4) not controlled to save (b) (4) data on it's (b) (4) of medical device kits, (b) (4) (b) (4).

b. There is no records or data to show the maintenance work done on (b) (4). These (b) (4) (b) (4) are used to (b) (4) in the (b) (4) in clean room (b) (4) and (b) (4).

c. There is no record of acceptance measurements conducted for (b) (4) used on (b) (4) (b) (4). For example, I observed (b) (4) were in use for material code (b) (4). There is no record of acceptance measurements. These (b) (4) have been in use since FEBRUARY 2015.

OBSERVATION 7

Procedures for monitoring and control of process parameters for a validated process have not been adequately established.

Specifically, your (b) (4) and Auditing Procedure, (b) (4), Effective 24 MAY 2018, uses simulated product rather than actual batch production kits. This (b) (4) audit procedure is conducted monthly and references (b) (4) to establish and verify sterility (b) (4) of medical devices (b) (4).

*DATES OF INSPECTION

4/17/2023(Mon), 4/18/2023(Tue), 4/19/2023(Wed), 4/20/2023(Thu), 4/21/2023(Fri), 4/24/2023(Mon), 4/25/2023(Tue)

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X Scott T Ballard
National Expert
Signed By: Scott T. Ballard -S
Date Signed: 04-25-2023 13:52:09

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Annotations to Observations

Observation 1: Not annotated

Observation 2: Not annotated

Observation 3: Not annotated

Observation 4: Not annotated

Observation 5: Not annotated

Observation 6: Not annotated

Observation 7: Not annotated

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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."