DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	3/9/2026-3/12/2026* FEI NUMBER 3016966810

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michael F. McCabe, VP of Operations

FIRM NAME	STREET ADDRESS
Altor Safety	711 Executive Blvd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Valley Cottage, NY 10989-2014	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

The quality management system was not documented in accordance with applicable regulatory requirements.

Specifically, your firm has not documented procedures and records for the operation and control of your quality management system processes. For example, your firm has not documented procedures and records for the following processes: Documentation Requirements; Management Responsibility; Resource Management; Product Realization; and Measurement, analysis, and improvement.

OBSERVATION 2

Medical device files have not been established and maintained.

Specifically, your firm has not established a medical device file for your firm's 3-ply (K211249) or 4-ply (K211762) surgical masks.

OBSERVATION 3

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Andrew J Garufi, Investigator X Andrew J Garufi Investigator Signed By: 2001292217 Date Signed: 03-12-2026 14:21:12	3/12/2026

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Processes for production and service provision where the resulting output cannot be, or is not, verified by subsequent monitoring or measurement were not validated.

Specifically, during the inspection (b) (4) mask machines (model numbers (b) (4) and (b) (4) were observed in your (b) (4) area actively manufacturing 3-ply (K211249) and 4-ply (K211762) surgical masks. However, your firm has not conducted a process validation study (IQ-OQ-PQ) on any of the these (b) (4) machines.

OBSERVATION 4

A design and development file was not maintained for each medical device type or medical device family.

Specifically, your firm has not established a design and development file for your firm's 3-ply (K211249) or 4-ply (K211762) surgical masks.

OBSERVATION 5

Written MDR procedures have not been developed.

Specifically, your firm has not documented procedures for assessing and reporting adverse events to the FDA as medical device reports (MDRs).

***DATES OF INSPECTION**

3/09/2026(Mon), 3/12/2026(Thu)

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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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Andrew J Garufi, Investigator

X Andrew J Garufi
Investigator
Signed By: 2001292217
Date Signed: 03-12-2026
14:21:12

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3/12/2026

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."