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	7/7/2026-7/9/2026
	FEI NUMBER 3041244757

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Catherine A. Copplestone, Operations Manager

FIRM NAME	STREET ADDRESS
ARTAFLEX BUFFALO INC	550 Colvin Ave
CITY, STATE, ZIP CODE, COUNTRY Buffalo, NY 14216	TYPE ESTABLISHMENT INSPECTED Medical Device Contract 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

Production controls do not include implementation of defined operations for labeling and packaging.

Specifically, procedures have not been documented for the printing and inspection of labels for the (b) (4) Additionally, labels applied to (b) (4) do not include the "RX Only" symbol as required by the label specification.

OBSERVATION 2

Procedures to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation, and disposition of nonconforming product were not adequately documented.

Specifically, Control of Nonconformity, QMP-003, Revision 3.6 requires nonconformances to be evaluated for the need for an investigation, however this requirement was not adequately implemented as 4 of 7 nonconformances reviewed included an evaluation determining a need for a review by the supplier of the nonconforming parts but did not include any documentation of a review or investigation.

OBSERVATION 3

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Matthew D Schnittker, Investigator	X Matthew D Schnittker Investigator Signed By: Matthew D. Schnittker -S Date Signed: 07-09-2026 13:51:19	7/9/2026

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Buffalo, NY 14216	Medical Device Contract Manufacturer

One or more processes for risk management in product realization have not been adequately documented.

Specifically, QMP-010 Risk Management, Rev 1.4 is inadequate as it does not clearly require the identification of potential failure modes related to all manufacturing processes or the identification of potential harms to end users or patients associated with the potential failure modes. Additionally, the process failure modes and effects analysis completed covering the processes used in the manufacture of (b) (4) does not identify potential harms to patients or end users associated with identified potential failure modes. In addition, the process failure modes and effects analysis is generalized and does not identify specific potential failures in the firm's processes which could lead to harm.

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Matthew D Schnittker, Investigator

X Matthew D Schnittker
Investigator
Signed By: Matthew D. Schnittker
-S
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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: 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."