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	2/17/2026-2/20/2026
	FEI NUMBER 1317202

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Stafford J. Frearson, President

FIRM NAME	STREET ADDRESS
Tessy Plastics Corp.	488 State Route 5
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Elbridge, NY 13060-9621	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

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

Specifically, risk management procedures documented in 2.4 Risk Management, SOP-ENG-0004, Revision A are inadequate as it does not provide adequate guidance for performing risk management activities related to manufacturing operations such as for developing process failure modes and effects analyses. Additionally, the process failure mode and effects analysis documented for the automated assembly process used for (b) (4) is inadequate as it does not identify harms associated with identified failure modes, it identifies three risk categories but does not define which categories require further risk mitigation, and does not define how the RPN used in determining the risk category is determined. In addition, no risk analysis was documented for the (b) (4) molding processes used to manufacture (b) (4) used in the manufacture of (b) (4)

OBSERVATION 2

Nonconforming product was accepted by concession without providing adequate justification, obtaining approval, and meeting applicable regulatory requirements.

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: 02-20-2026 07:52:00	2/20/2026

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Specifically, 3 of 7 nonconformances reviewed had a disposition to use as is but did not include documented justification. Additionally, nonconforming material procedures documented in 14.1 Non-Conform, SOP-NCR-0001, Revision F requires customer approval for a disposition of use as is but does not clearly require documented justification.

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Annotations to Observations

Observation 1:

Observation 2:

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	Matthew D Schnittker, Investigator X Matthew D Schnittker Investigator Signed By: Matthew D. Schnittker -S Date Signed: 02-20-2026 07:52:00	2/20/2026

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."