DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
109 Holton Street Winchester, MA 01890 (781)587-7500 Fax:(781)587-7556	6/4/2026-6/11/2026* FEI NUMBER 3007034244

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Paul Discoe, Quality Manager

FIRM NAME	STREET ADDRESS
Hi Tech Mold & Tool, Inc.	1 Technology Dr W
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Pittsfield, MA 01201-8222	Medical Device

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

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,

A. Your firm manufactures (b) (4) Systems in multiple product codes including (b) (4). Your firm's only process validation for the (b) (4) process, TR-220292, IQ/OQ/PQ, covers product code (b) (4) only, manufactured on (b) (4) only. No process validation exists for the other (b) (4) product codes.

B. The Performance Qualification for product code (b) (4), TR-220292, July 12, 2007, did not meet the established (b) (4) target of (b) (4). The PQ report states: "This target could not be achieved during PQ execution since some of dimensions are out of specification." The PQ conditioned production release on drawing revisions that your firm could not confirm as completed.

C. No process validation has been performed for (b) (4), utilized in the (b) (4) of (b) (4). The (b) (4) process for (b) (4) is performed using Press (b) (4), Serial No. (b) (4) in addition to Press (b) (4) Serial No. (b) (4). Although

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jeffrey J Thibodeau, Investigator X Jeffrey J Thibodeau Investigator Signed By: JEFFREY J. THIBODEAU -S Date Signed: 06-11-2026 15:51:04	6/11/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
109 Holton Street Winchester, MA 01890 (781)587-7500 Fax:(781)587-7556	6/4/2026-6/11/2026*
	FEI NUMBER 3007034244

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Paul Discoe, Quality Manager

FIRM NAME	STREET ADDRESS
Hi Tech Mold & Tool, Inc.	1 Technology Dr W
CITY, STATE, ZIP CODE, COUNTRY Pittsfield, MA 01201-8222	TYPE ESTABLISHMENT INSPECTED Medical Device

your firm's management stated that (b) (4) and (b) (4) are equivalent machines, no documented equivalency study or process capability data was performed.

***DATES OF INSPECTION**
6/04/2026(Thu), 6/05/2026(Fri), 6/10/2026(Wed), 6/11/2026(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jeffrey J Thibodeau, Investigator X Jeffrey J Thibodeau Investigator Signed By: JEFFREY J. THIBODEAU -S Date Signed: 06-11-2026 15:51:04	6/11/2026

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
109 Holton Street Winchester, MA 01890 (781)587-7500 Fax:(781)587-7556	6/4/2026-6/11/2026*
	FEI NUMBER 3007034244

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Paul Discoe, Quality Manager

FIRM NAME	STREET ADDRESS
Hi Tech Mold & Tool, Inc.	1 Technology Dr W
CITY, STATE, ZIP CODE, COUNTRY Pittsfield, MA 01201-8222	TYPE ESTABLISHMENT INSPECTED Medical Device

Annotations to Observations

Observation 1: Promised to correct

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jeffrey J Thibodeau, Investigator	X Jeffrey J Thibodeau Investigator Signed By: JEFFREY J. THIBODEAU -S Date Signed: 06-11-2026 15:51:04	6/11/2026

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."