**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 1201 Main Street, Suite 7200<br>Dallas, TX 75202<br>(214)253-5200 Fax:(214)253-5314 | 6/1/2026-6/3/2026 |
| | FEI NUMBER<br>3000985188 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Brenda C. McCain, National Accounts Manager

| FIRM NAME | STREET ADDRESS |
|---|---|
| ITI Manufacturing, Inc. | 333 Southwestern Blvd Ste 202 |
| CITY, STATE, ZIP CODE, COUNTRY<br>Sugar Land, TX 77478-3659 | TYPE ESTABLISHMENT INSPECTED<br>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.

**DURING AN INSPECTION OF YOUR FIRM I OBSERVED:**

## OBSERVATION 1

Records of the nature of nonconforming product and any subsequent action taken, including the evaluation, and any investigation and the rationale for decisions, were not maintained.

Specifically, during a review of the Inspection Report for the (b) (4) model with (b) (4), Production Date (b) (4), it was observed a total of (b) (4) defective units were identified. Your firm's Inspection Requirements, F-QMT-04MSL, Rev. 1, effective 01/05/2021, stated the maximum acceptable defect rate for minor defects is (b) (4)

Your firm's procedure Control of Nonconforming Product, P-JMP-07, Rev. 2, 04/10/2021, requires nonconforming product to be recorded with the form Product Nonconformity, F-JMP-13, effective 01/22/2003. However, the order was marked as accepted and no further documentation was provided for these defective units.

Your firm's National Accounts Manager stated the defective units were rejected and reworked into conformance; however, your firm did not have documentation for the identified nonconforming products and any subsequent actions taken, including the rework and verification of the reworked units.

## OBSERVATION 2

Control over outsourced processes that affect product conformity to requirements do not include written quality agreements.

Specifically, your firm's procedure Supplier Evaluation & Management, P-JMP-02, Rev. 2, effective

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Yuliana Hernandez-Magana, Investigator<br>X Yuliana Hernandez-Magana Investigator Signed By: YULIANA HERNANDEZ-MAGANA -S Date Signed: 06-03-2026 11:37:43 | 6/3/2026 |

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04/10/2021, does not include requirements for written quality agreements to ensure product conformity. For example, your firm does not have a written quality agreement with the manufacturer of the Class II (b) (4) .

**OBSERVATION 3**

Procedures to describe the responsibilities and requirements for planning and conducting internal audits and recording and reporting audit results were not adequately documented.

Specifically, your firm's quality manual ML830 Device Quality Management Systems (QM) Manual, QMS-ML, Rev. 2, effective 12/31/2022, section 2.3 Quality Audit, requires internal audits to be conducted (b) (4) However, your firm has not performed an internal audit since 2003, when the firm began medical device operations.

Additionally, section 2.3 Quality Audit does not contain requirements for audit criteria, scope, methods, or auditor objectivity and impartiality.

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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."