

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

DISTRICT ADDRESS AND PHONE NUMBER 6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410) 779-5455 Fax: (410) 779-5707	DATE(S) OF INSPECTION 4/29/2019-5/10/2019*
	FEI NUMBER 3011660613

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jeffrey B. Miller, General Manager

FIRM NAME Tecomet, Inc.	STREET ADDRESS 7145 Colonial Ln
----------------------------	------------------------------------

CITY, STATE, ZIP CODE, COUNTRY Pennsauken, NJ 08109-4314	TYPE ESTABLISHMENT INSPECTED 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

Procedures for finished device acceptance have not been adequately established.

Specifically,

Your firm failed to ensure finish products that failed testing were not distributed. For example, work order (b) (4) contained a corrosion test certificate marked "Yes" for corrosion detected. The (b) (4) unit lot of 3.9mm (b) (4) drills were signed by quality confirming all testing was satisfactorily completed and given a certification of compliance. The lot was shipped to the customer 11/16/18.

OBSERVATION 2

Procedures for the acceptance and control of in-process product have not been adequately established.

Specifically,

Your firm failed to conduct the passivation processing as per your procedures. For example, a review of passivation records from 2019 found four occasions where medical devices were at least 3 degrees below the specified temperature in the procedures. Of the four, passivation records indicate one work

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Tiki Dixon, Investigator	Tiki Dixon Investigator Signed By: 2000441527 Date Signed: 05-10-2019 12:30:06 X _____	DATE ISSUED 5/10/2019

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

DISTRICT ADDRESS AND PHONE NUMBER 6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410) 779-5455 Fax: (410) 779-5707	DATE(S) OF INSPECTION 4/29/2019-5/10/2019*
	FEI NUMBER 3011660613

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jeffrey B. Miller, General Manager

FIRM NAME Tecomet, Inc.	STREET ADDRESS 7145 Colonial Ln
CITY, STATE, ZIP CODE, COUNTRY Pennsauken, NJ 08109-4314	TYPE ESTABLISHMENT INSPECTED Contract Manufacturer

order, (b) (4) for (b) (4) units of the class II component 1-72 tension screw, was distributed on 3/11/19.

OBSERVATION 3

Procedures for corrective and preventive action have not been adequately established.

Specifically,

A. Your firm failed to open a CAR when a process problem was found. For example, NCMR #N18-013 identified a problem with work order process steps being incorrect. The firm investigated the problem and implemented a solution without opening a CAR.

- B. Your firm failed to open a CAR when complaints were accompanied with a NCMR. For example:
- Complaint #CC17-040 identified a problem, via complaint, with stains on straight plates. A NCMR was received from the customer. The firm's form was not completed for the complaint and a CAR was not initiated to investigate the problem.
 - Complaint #CC17-037 identified a problem, via complaint, with stains on straight plates. A NCMR was received from the customer. The firm's form was not completed for the complaint and a CAR was not initiated to investigate the problem.

C. Your firm failed to adequately identify and document the actions needed to correct and prevent the recurrence of problems. For example:

- CAR #C18-009 identified problems, via complaint, with edge and surface defects, true position measurement problems, and wrong items shipped with correct order. Documentation addressing any training or re-training was not found.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Tiki Dixon, Investigator	Tiki Dixon Investigator Signed By: 2000441527 Date Signed: 05-10-2019 12:30:06 X _____	DATE ISSUED 5/10/2019

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

DISTRICT ADDRESS AND PHONE NUMBER 6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410) 779-5455 Fax: (410) 779-5707	DATE(S) OF INSPECTION 4/29/2019-5/10/2019*
	FEI NUMBER 3011660613

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jeffrey B. Miller, General Manager

FIRM NAME Tecomet, Inc.	STREET ADDRESS 7145 Colonial Ln
----------------------------	------------------------------------

CITY, STATE, ZIP CODE, COUNTRY Pennsauken, NJ 08109-4314	TYPE ESTABLISHMENT INSPECTED Contract Manufacturer
-------------------------------------------------------------	-------------------------------------------------------

- CAR #C19-003 identified a problem, via complaint, with a tang auto click failing a pin gauge test. Documentation addressing any training or re-training was not found.
- CAR #C18-017 identified a problem, via complaint, with threads failing go/no go testing. Documentation addressing any training or re-training was not found.
- CAR #C19-002 identified a problem, via complaint, with scratches, pits, and grit on the surface of plate holes. Documentation addressing any training or re-training was not found.

OBSERVATION 4

Procedures for acceptance of incoming product have not been adequately established.

Specifically,

Your firm failed to follow procedures to properly identify inspected raw material from raw materials that were not inspected. For example, the following raw material was found in the inspected location without an "ACCEPTED" label sticker:

- Lot #(b) (4))
- Lot #(b) (4))
- Lot #(b) (4))
- Lot #(b) (4))

OBSERVATION 5

Procedures to ensure equipment is routinely calibrated have not been adequately established.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Tiki Dixon, Investigator	Tiki Dixon Investigator Signed By: 2000441527 Date Signed: 05-10-2019 12:30:06 X _____	DATE ISSUED 5/10/2019

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

DISTRICT ADDRESS AND PHONE NUMBER 6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410) 779-5455 Fax: (410) 779-5707	DATE(S) OF INSPECTION 4/29/2019-5/10/2019*
	FEI NUMBER 3011660613

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jeffrey B. Miller, General Manager

FIRM NAME Tecomet, Inc.	STREET ADDRESS 7145 Colonial Ln
----------------------------	------------------------------------

CITY, STATE, ZIP CODE, COUNTRY Pennsauken, NJ 08109-4314	TYPE ESTABLISHMENT INSPECTED Contract Manufacturer
-------------------------------------------------------------	-------------------------------------------------------

Specifically,

Your firm failed to ensure calibration of all measuring equipment. For example, clampmeter #274 was due to be calibrated 3/2018. The device was not calibrated until 8/2018 without any justification.

***DATES OF INSPECTION**

4/29/2019(Mon), 4/30/2019(Tue), 5/01/2019(Wed), 5/02/2019(Thu), 5/03/2019(Fri), 5/10/2019(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Tiki Dixon, Investigator	<small>Tiki Dixon Investigator Signed By: 2000441527 Date Signed: 05-10-2019 12:30:06</small> X _____	DATE ISSUED 5/10/2019

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

DISTRICT ADDRESS AND PHONE NUMBER 6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410) 779-5455 Fax: (410) 779-5707	DATE(S) OF INSPECTION 4/29/2019-5/10/2019*
	FEI NUMBER 3011660613

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jeffrey B. Miller, General Manager

FIRM NAME Tecomet, Inc.	STREET ADDRESS 7145 Colonial Ln
----------------------------	------------------------------------

CITY, STATE, ZIP CODE, COUNTRY Pennsauken, NJ 08109-4314	TYPE ESTABLISHMENT INSPECTED Contract Manufacturer
-------------------------------------------------------------	-------------------------------------------------------

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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Tiki Dixon, Investigator	<small>Tiki Dixon Investigator Signed By: 2000441527 Date Signed: 05-10-2019 12:30:06</small> X _____	DATE ISSUED 5/10/2019