DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	3/3/2026-3/6/2026
	FEI NUMBER 2013558

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mark S. Mettler, President

FIRM NAME	STREET ADDRESS
Mettler Electronics Corp	1333 S Claudina St
CITY, STATE, ZIP CODE, COUNTRY Anaheim, CA 92805-6235	TYPE ESTABLISHMENT INSPECTED 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 to ensure that purchased product conforms to specified purchasing information have not been adequately documented.

Specifically, your firm's procedure QP-005, Supplier Qualification and Rating states: "Quality Agreement is needed for critical (b) (4) suppliers. A signed contract/agreement shall be done before placing the first PO." Your firm was unable to provide documentation of quality agreements for (b) (4) critical suppliers for components of the Sonicator 740.

In addition, QP-005 also states "Both QS and Purchasing Manager should ensure the rotation of suppliers selected for audit to ensure all critical (b) (4) suppliers are audited every (b) (4)." Your firm was unable to provide documentation to show supplier audits were conducted for three of the (b) (4) critical suppliers. The (b) (4) critical supplier had its last supplier audit conducted in 2018.

OBSERVATION 2

Corrective action was not adequately taken to eliminate the cause of nonconformities in order to prevent recurrence.

Specifically, your firm's procedure, QP-001V, Corrective Action & Preventive Action (CAPA) Program,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jae H Lee, Investigator X Jae H Lee Investigator Signed By: 2004444300 Date Signed: 03-06-2026 10:34:03	3/6/2026

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Revision V, Effective Date: 05/11/2022, lists potential CAPA information sources which includes: "non-conformances from outside agency audits and inspections; and any other source relevant to the safety and effectiveness of Mettler products and processes."

Your firm did not conduct root cause analysis or implement corrective actions to address the causes of the nonconformities identified during the previous inspection conducted in September 2023. Your firm did not conduct adequate investigation, retrospective reviews, or take a systemic evaluation to determine and address the cause of the four FDA 483 observations and two discussion items.

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: 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."