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	3/3/2026-3/5/2026
	FEI NUMBER 1000098753

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mark J. Meinecke, Vice President of Quality Assurance

FIRM NAME	STREET ADDRESS
Moldex-Metric, Inc.	10111 Jefferson Blvd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Culver City, CA 90232-3509	Medical Device 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 risk management activities in product realization were not maintained.

For example, your site does not maintain Risk Analysis Record for N95 Healthcare and Surgical Mask Family of Product to control and monitor risks.

OBSERVATION 2

A design and development file was not maintained for each medical device type or medical device family.

Specifically, per your firm's Design and Development Procedure (Product Design Control and Review-Doc. 410001, Rev.14) a Design and Development File has not been maintained for Class II Moldex N95 Healthcare and Surgical Mask Family of Product (i. e. 1500, 4150 & 4650 Series) that your firm currently manufactures.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Sarah A Hassas, Investigator X Sarah A Hassas Investigator Signed By: Sarah A. Hassas -S Date Signed: 03-05-2026 11:29:47	3/5/2026

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Not annotated

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Sarah A Hassas, Investigator

X Sarah A Hassas
Investigator
Signed By: Sarah A. Hassas -S
Date Signed: 03-05-2026
11:29:47

DATE ISSUED
3/5/2026

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."