DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301)594-4695 Fax:(301)594-4715	1/12/2026-1/15/2026 FEI NUMBER 3012855798

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kingsley Hall, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Micro-X Ltd.	Unit 14 6 Mab Eastern Promenade
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Tonsley, South Australia, 5042 Australia	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 design change have not been adequately established.

Specifically, your firm did not adequately implement design change procedure *SOP002 Change Control*. Your firm conducted a field correction, Recall #Z-1578-2025 and Z-1579-2025, to address early life tube failures. The correction involved updating the values of the current (mA) and exposure time (ms) in the Generator Lookup Table to improve thermal management through Change Notice CN184-24, approved on 12/20/2024. This update was implemented on field units beginning 02/18/2025 under installation instructions Modification MOD2408, version 1.0. However, your firm did not conduct design change verification or validation prior to implementing this field correction to ensure, for example, that the updated Generator Lookup Table values are accurate, the software correctly retrieves and translates these values into proper generator control signals, the X-ray output maintains acceptable image quality, and the modifications improve tube life. Additionally, the installation instructions in Modification MOD2408, version 1.0, were not validated, resulting in inadequate instructions that necessitated a revision to Modification MOD2408, version 1.1, which was subsequently released under Change Notice CN095-25 on 07/03/2025.

OBSERVATION 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Karen M Cruz Arenas, Investigator	X Karen M Cruz Arenas Investigator Signed By: KAREN M. CRUZ ARENAS -S Date Signed: 01-15-2026 15:01:29	1/15/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301)594-4695 Fax:(301)594-4715	1/12/2026-1/15/2026 FEI NUMBER 3012855798

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kingsley Hall, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Micro-X Ltd.	Unit 14 6 Mab Eastern Promenade
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Tonsley, South Australia, 5042 Australia	Manufacturer

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically, Your firm has not adequately implemented your complaint handling procedure *SOP 007 Customer Complaint Management*. A review of [redacted] tickets sampled from [redacted] tickets in the Field Service Board (FSB) from June 2024 – January 2026, identified 21 tickets that were not deemed as complaints and were not recorded on the Customer Complaint Form FSOP007A to determine the need for an investigation and for further evaluation for Medical Device Reporting for the alleged malfunction. The following are example of these FSB tickets:

Ticket #	Date created	Description	Serial #
FSB-1436	5/20/2025	Unit failed due to arcing during exposure testing	(b)(4)
FSB-1435	5/20/2025	Unit failed due to arcing during exposure testing	
FSB-1432	5/20/2025	Unit failed during exposure testing	
FSB-1050	10/8/2024	Battery critical error	
FSB-1208	2/7/2025	Equipment reliability not up to the mark	unknown

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Karen M Cruz Arenas, Investigator	X Karen M Cruz Arenas Investigator Signed By: KAREN M. CRUZ ARENAS -S Date Signed: 01-15-2026 15:01:29	1/15/2026

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301)594-4695 Fax:(301)594-4715	1/12/2026-1/15/2026 FEI NUMBER 3012855798

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Kingsley Hall, Chief Executive Officer	
FIRM NAME Micro-X Ltd.	STREET ADDRESS Unit 14 6 Mab Eastern Promenade
CITY, STATE, ZIP CODE, COUNTRY Tonsley, South Australia, 5042 Australia	TYPE ESTABLISHMENT INSPECTED Manufacturer

Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Karen M Cruz Arenas, Investigator	X Karen M Cruz Arenas Investigator Signed By: KAREN M. CRUZ ARENAS -S Date Signed: 01-15-2026 15:01:29	DATE ISSUED 1/15/2026

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."