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	8/26/2025-8/29/2025
	FEI NUMBER 3008034554

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Alan T. Graham, Chief Operating Officer

FIRM NAME	STREET ADDRESS
XL PRECISION TECHNOLOGIES LTD	79 Sadler Forster Way
CITY, STATE, ZIP CODE, COUNTRY Stockton-On-Tees, Cleveland, TS17 9JY United Kingdom	TYPE ESTABLISHMENT INSPECTED 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.

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 corrective and preventive action have not been adequately established.

Specifically,

A. You have not fully implemented your procedures for Corrective and Preventive Action, XL QP 006, defining requirements for investigation of identified quality problems and determine the underlying causes. For example,

i. Your record for CAPA No. 2025/002, initiated 01-AUG-2025, was opened in part to respond to the finding that your Goods In Process did not accurately list the persons responsible for the receiving process and a finding that you were unable to locate the training records for the persons responsible for the receiving process. The record does not list a complete investigation to determine the underlying causes for these quality problems, and the record does not list any actions proposed to address these two quality problems.

ii. Your CAPA record for Nonconforming Product Record No. 1079/2025, dated 07-JUN-2025, was opened in response to a finding that the verification for accuracy of the (b)(4)

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	Joshua J Silvestri, Investigator	X Joshua J Silvestri Investigator Signed By: JOSHUA J. SILVESTRI -S Date Signed: 08-29-2025 17:49:08	8/29/2025

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(b)(4)

(b)(4) The record does not list a full investigation to determine the underlying causes for this quality problem, to include determining the reason this equipment maintenance software was **not** validated for the purpose of identifying out of specification measurements. Further, you currently do not have a written procedure defining requirements for validating software that is not used to control production of devices, including but not limited to software used for equipment maintenance tasks.

B. Your current procedure for Corrective and Preventive Action, XL QP 006, Rev I, does not define requirements or a process for implementing the actions that are identified to prevent recurrence of existing quality problems.

C. You do not have a written procedure defining requirements to control identification of potential quality problems, to control the investigation of such problems, to identify actions intended prevent such problems, and to evaluate and implement such actions.

OBSERVATION 2

A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures.

Specifically,

A. Your records for the effort to validate the passivation process utilized to manufacture the

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[redacted] laser-marked at your factory, validation report dated 20th June 2019, do not define the method utilized to evaluate the devices processed under the Operational Qualification (OQ) and the Performance Qualification (PQ) to confirm those devices were acceptably resistant to corrosion following completion of the process. Further, this validation report lists a reference to use of the acceptance criteria defined under the ASTM A967 standard test method but does not list use of the complete test method described under the standard, and you do not have records demonstrating use of the test method for evaluation of the devices processed under the OQ and PQ efforts.

Further, the Operational Qualification effort did not characterize the process for variation in results of the passivation process related to differences in the number of devices processed in each passivation batch, and the Performance Qualification effort did not define and examine the normal variation in batch size.

i. Production records for Work Order 21357 processed 07-MAY-2021 and Work Order 24336 processed 07-DEC-2022 were each batches of more than twice the number of devices processed under this PQ effort.

ii. Production records for W.O. 23309 processed 04-APR-2022 and W.O. 23310 processed 04-APR-2022 were each batches slightly more than half the number of devices processed under this PQ effort.

B. You have not defined and documented written procedures for validation of all software utilized under the quality system, to include the software utilized to log and evaluate maintenance activities.

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OBSERVATION 3

Procedures for monitoring and control of process parameters for a validated process have not been adequately established.

Specifically,

A. Your current written procedure for the passivation process, used to manufacture the reverse-[(b)(4)] device laser-marked at your factory, XL ~~QP~~ **WI** 007, Rev E, does not list the settings for the critical process parameters of Temperature and acid concentration as were evaluated under the Performance Qualification (PQ) carried out to validate the passivation process.

B. Your records of the passivation process for the [(b)(4)] laser-marked at your factory, Part Nos. [(b)(4)] do not list the [--] concentration used to process each passivation batch.

Further, the XL ~~QP~~ **WI** 007 work instruction does not define the number of devices to process per passivation batch, and production records for Work Order 21357 processed 07-MAY-2021 and Work Order 24336 processed 07-DEC-2022 show each batch consisted of twice the number of devices as were processed under the Performance Qualification effort covering the passivation process during 2019.

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Annotations to Observations

Observation 1: Not annotated

Observation 2: Not annotated

Observation 3: Not annotated

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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."