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	10/27/2025-10/29/2025
	FEI NUMBER 3008856394

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Ryszard Stepniak, Owner Operator

FIRM NAME	STREET ADDRESS
Clavmed	Tuszyn 40
CITY, STATE, ZIP CODE, COUNTRY Tuszyn , Dolnoslaskie, 58-207 Poland	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

Quality system procedures and instructions have not been established.

Specifically, the firm does not have written Quality System procedures, instructions and records, including, but not limited to quality audits, change controls, identification and traceability, nonconforming products, process validation, process monitoring, calibration, preventive maintenance, labeling and packaging controls, handling, storage and distribution, complaint handling, sampling, and acceptance procedures.

The firm is the exclusive contract manufacturer of variety of K-Wires and Steinmann Pins for (b)(4) (b)(4). The devices are intended to fix fracture, aide in bone realignment, stabilization of broken bone, and provide traction and guide for other orthopedic implants. The devices are only marketed and distributed in the United States.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Maryam Tabatabaie, Investigator X Maryam Tabatabaie Investigator Signed By: Maryam Tabatabaie -S Date Signed: 10-29-2025 11:42:47	10/29/2025

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Annotations to Observations

Observation 1:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Maryam Tabatabaie, Investigator	X Maryam Tabatabaie Investigator Signed By: Maryam Tabatabaie -S Date Signed: 10-29-2025 11:42:47	10/29/2025

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."