DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	6/9/2026-6/11/2026
	FEI NUMBER 3010131715

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kerriann R. Greenhalgh, Owner

FIRM NAME	STREET ADDRESS
KeriCure Inc.	(b) (6), (b) (7)(C)
CITY, STATE, ZIP CODE, COUNTRY (b) (6), (b) (7)(C)	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

Records of risk management activities in product realization were not maintained.

Specifically, the firm designated DC-104-1a (Risk Management Plan — Field Shield, Version 1, dated 07/31/2023) as the device-level risk management plan for the Field Shield Wound Dressing; however, this document is a general organizational risk and opportunity management procedure that does not constitute a device-level risk management plan. The firm's Hazard Analysis does not evaluate residual risk after the application of risk controls, does not include an overall residual risk evaluation, does not address all reasonably foreseeable hazards associated with the device's active ingredients, and is not supported by a completed risk management report.

OBSERVATION 2

Records of the results and conclusion of validation of processes and necessary actions from the validation were not maintained.

Specifically, on 06/09/2026, the firm provided [Process Validation Report - KeriCure Field Shield, V24-003R as evidence of process validation for the Field Shield Wound Dressing. Upon review, the process validation report was found to be unsigned and undated by the responsible approving personnel. The signature and date fields

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Ulysses D Singleton, Investigator X Ulysses D Singleton Investigator Signed By: ULYSSES D. SINGLETON III -S Date Signed: 06-11-2026 09:49:56	6/11/2026

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designated for the Technical Director, Manufacturing Representative, Quality Assurance, and Customer Representative on the document cover page were blank at the time of review. The firm was unable to provide evidence that the process validation report had been formally reviewed, approved, and authorized by qualified personnel prior to implementation of the validated process.

OBSERVATION 3

Records needed to demonstrate compliance with applicable regulatory requirements have not been adequately established and maintained.

Specifically, on 06/09/2026, I collected and reviewed the firm's Quality Policy (QA-006, Rev: 2a, Effective: 07/31/2023), the Medical Device Master Record, and associated quality system documentation. The firm's Quality Management System documentation does not reference the QMSR (21 CFR Part 820, effective February 2, 2026) or ISO 13485:2016 as the governing regulatory framework. All quality system procedures reviewed continue to reference the legacy Quality System Regulation (21 CFR Part 820, pre-February 2, 2026) and its subparts, which were superseded on February 2, 2026. The firm has not updated its quality system documentation to reflect the current regulatory requirements under the QMSR.

OBSERVATION 4

Procedures for timely complaint handling have not been adequately documented.

Specifically, QA-011-1a (Complaint Handling Procedure, Version 1a) fails to include requirements and responsibilities for the following: (a) receiving and recording complaints from all known distribution channels, including the firm's Amazon sales portal; (b) handling of complaint-related product; (c) timely processing of complaints including defined time frames for initial complaint review and investigation completion; and (d) use of complaint data as input into the firm's risk management process;

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EMPLOYEE(S) SIGNATURE
Ulysses D Singleton, Investigator

X Ulysses D Singleton Investigator Signed By: ULYSSES D. SINGLETON III -S Date Signed: 06-11-2026 09:49:56

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

Observation 4: 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."