DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612)334-4100 Fax:(612)334-4134	5/11/2026-5/13/2026
	FEI NUMBER 3025308469

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Joseph A. Paul, Chief Technological Officer

FIRM NAME	STREET ADDRESS
Lucas Lifecare LLC	2302 Beloit Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Janesville, WI 53546-3051	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

Internal audits have not been conducted at planned intervals to determine whether the QMS conforms to planned and documented arrangements and applicable requirements and is effectively implemented and maintained.

Specifically,

Per Internal Quality Audit Procedure, LL-QSP-07, Rev 01, 07/05/2022, page 10 section 8, internal audit programs are to be conducted (b) (4) However, your organization has not planned or conducted internal audits since 2024.

Per Internal QMS Audit Check List – Production, MR-SOP-06, Rev 01, 9/26/2024, your organization is required to (b) (4) available for manufacturing related activities of a product. Your organization did not conduct internal audits to determine whether your organization's non-conforming procedures have been adequately implemented and maintained. For example:

A. Per Internal QMS Audit Check List – Production, MR-SOP-06, Rev 01, 9/26/2024, your organization is required to (b) (4) in your product batch records. Per Control of Non-Conforming Products Procedure, LL-QSP-37, Rev 01, 07/05/2022, page 13 section 9.2,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Shawn Choi, Investigator X Shawn Choi Investigator Signed By: 2004265134 Date Signed: 05-13-2026 12:59:54	5/13/2026

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Joseph A. Paul, Chief Technological Officer	
FIRM NAME Lucas Lifecare LLC	STREET ADDRESS 2302 Beloit Ave
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non-conformities can be observed during assembly and test processes which are to be identified and documented. Per Liferay Certificate of Conformance, 04/29/2026 for the LifeRay Handheld X-ray device, unit (b) (4) , the testing for consistency of radiation failed; however, your organization documented this failure as a complaint and not a non-conformance.

B. Per Control of Non-Conforming Products Procedure, LL-QSP-37, Rev 01, 07/05/2022, page 15 section 9.3, non-conforming product identified at customer facility or after delivery are to be documented and to be evaluated for rework. Your organization did not document your returned LifeRay Handheld X-ray devices as non-conformances after receiving complaints from your customers.

OBSERVATION 2

Criteria for the evaluation of suppliers were not adequately established.

Specifically,

Your organization has not established a criterion for how often critical suppliers are to be audited. Your organization established a supplier agreement with a critical supplier in 2023 for the LifeRay Handheld X-ray device, and there have been no supplier audits conducted with the critical supplier.

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: 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."