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	2/3/2026-2/6/2026
	FEI NUMBER 3010396502

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Scott B. Petrunick, CEO/President

FIRM NAME	STREET ADDRESS
CAREstream Medical Ltd	200 Technology Park Ste 1040
CITY, STATE, ZIP CODE, COUNTRY Lake Mary, FL 32746-7136	TYPE ESTABLISHMENT INSPECTED Medical DEeviced 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

The quality management system was not documented in accordance with applicable regulatory requirements.

Specifically, your firm's Quality Management System (QMS) is based upon requirements from the Quality System Regulation (QSR).

OBSERVATION 2

Top management did not ensure that applicable regulatory requirements were determined and met.

Specifically, Your firm also failed to hold annual management review meetings in 2023 and 2024.

OBSERVATION 3

Design and development procedures were not documented.

Specifically, your firm's Design and Development is inadequate in that it includes requirements found in 21 CFR 820.30.

OBSERVATION 4

Procedures for timely complaint handling have not been adequately documented.

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: 02-06-2026 09:04:49	2/6/2026

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Specifically, your firm's complaint handling procedure does not include requirements stated in the Quality Management System Regulation.

OBSERVATION 5

Software used in production and service provision was not validated prior to initial use and after changes to such software or its application.

Specifically, your firm failed to validate Quality Management System (QMS) software prior to its initial use.

OBSERVATION 6

The labels of the medical device(s) do not bear a unique device identifier (UDI) that meet the requirements of 801 Subpart B and 21 CFR 830.

Specifically, your firm's Identification and Traceability procedure does not contain the requirement for unique device identifier (UDI).

OBSERVATION 7

Records of the results of evaluation and selection of supplier capability or performance were not maintained.

Specifically, your firm failed to identify critical suppliers during supplier evaluation. The top 2 suppliers, on your Approved Supplier List (ASL), were not fully evaluated and the risk classification was not identified.

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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

Observation 5: Promised to correct

Observation 6: Promised to correct

Observation 7: 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."