DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	3/9/2026-3/13/2026
	FEI NUMBER 3012232668

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Joeie L. Clark, Vice President of Finance

FIRM NAME	STREET ADDRESS
Raumedic Inc	235 Broadpointe Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Mills River, NC 28759-4995	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.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Procedures for validation of processes did not adequately include approval of changes to the processes.

Specifically, your firm failed to provide documentation and approval for changing your validation test run from (b) (4) bowls.

As per your equipment qualification titled "Detailed scope of Equipment Qualification (b) (4) (b) (4) Document number: VA_RM_00018_FB_01, Version 5.0, dated 9/12/2024, states the following (b) (4) (b) (4)

Your test report titled: "Testrun (b) (4) , dated 11/6/2024, states the following (b) (4) (b) (4)

There was inadequate documentation for approval of the change in test run size from (b) (4) bowls.

OBSERVATION 2

Production and service provision was not adequately planned, carried out, monitored, and controlled to ensure that product conforms to specification.

Specifically, your firm failed to follow your procedure titled "Production Inspection Procedures", Version 5.0, Number: VA_6100_00036_EN, dated 5/29/2025. In section 5.3 it states "The quality technician will complete an inspection of assembled articles (b) (4) "... and "Results of these inspections will be recorded on the inspection protocol sheet.".

In the production record for subassembly (b) (4) part number: (b) (4) , batch number: (b) (4) dates of production 8/28 and 8/29/2025, there were no quality inspections documented on the inspection

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Alex J Wild, Investigator	X Alex J Wild Investigator Signed By: 2003425532 Date Signed: 03-13-2026 15:04:31	3/13/2026

protocol sheet.

OBSERVATION 3

Records of the verification of purchased product were not adequately maintained.

Specifically, your firm failed to retain the incoming inspection sample for (b) (4) Sample number: (b) (4) collected from batch number: (b) (4) vendor batch: (b) (4) material number: (b) (4) dated 11/03/2025.
In your (b) (4) system it showed that (b) (4) pieces arrived in the shipment; (b) (4) were labeled (b) (4) (b) (4), and (b) (4) was labeled (b) (4)
During the inspection your firm failed to locate the physical sample associated with this record.

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Annotations to Observations

Observation 1:

Observation 2:

Observation 3:

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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."