DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1777 Hardee Ave SW Atlanta, GA 30310 (404)253-1284 Fax:(404)669-4443	6/10/2026-6/12/2026
	FEI NUMBER 3008724689

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lois nmn Tsui, President

FIRM NAME	STREET ADDRESS
Comfortland Medical, Inc.	709 A O Smith Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Mebane, NC 27302-2752	Specification Developer

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

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

Specifically, your firm did not determine process controls, provide resources to control processes, or implement necessary actions for effective processes prior to June 8, 2026. Management did not ensure the availability of resources to establish and document processes for the Quality Management System. Management did not ensure that quality objectives are established for Design and Development, Purchasing, Production controls, Complaint handling, Control of Nonconforming product, Internal audits, Risk management, Corrective and Preventive actions processes and labeling product requirements.

OBSERVATION 2

Written MDR procedures have not been developed, maintained and implemented.

Specifically, your firm failed to implement a process for identifying, evaluating, documenting and reporting adverse events. In my review of three documented complaints for the Class II (b) (4) (b) (4) System, the device failed for (b) (4), while in use by patient, and suddenly stopped working while in use. These potential failures could lead to an interruption of prescribed (b) (4) or delay in treatment.

OBSERVATION 3

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Christopher B May, Investigator	X Christopher B May Investigator Signed By: CHRISTOPHER B. MAY -S Date Signed: 06-12-2026 14:48:16	6/12/2026

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A design and development file was not maintained for each medical device type or medical device family.

Specifically, your firm failed to maintain design and development documentation of the Class II (b) (4) System to demonstrate that it performs as intended. No design and development file has been created for the device. Furthermore, your firm does not have and records for design and development changes for the device, to include implementing procedures and maintaining records of when the labels on this devices were changed.

OBSERVATION 4

Processes needed for product realization were not planned and developed.

Specifically, your firm failed to plan and document the processes for risk management in product realization of the Class II (b) (4) System. No records of risk management activities have been maintained.

OBSERVATION 5

Complaint handling records were not adequately maintained.

Specifically, your firm failed to maintain records of receiving and evaluating complaints from customers since 2016 when the Class II (b) (4) System went on the market. Also, in my review of three complaint records provided, the firm did not conduct any investigations into the detailed problems of the complaints.

OBSERVATION 6

Controls over outsourced processes that affect product conformity to requirements are not proportionate to the risk involved and the ability of the external party to meet purchasing requirements.

Specifically, your firm failed to maintain the supplier of the Class II (b) (4)

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(b) (4) System by having procedures in place to evaluate the supplier of the device and to ensure the purchased product meets specified purchasing requirements. No record of product design specifications, acceptance procedures for the product, or monitoring of the suppliers performance has been maintained.

OBSERVATION 7

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 document and maintain procedures that provide a detailed description of the processes used to verify the Class I (b) (4) and Class II (b) (4) (b) (4) system products are inspected, processed, stored, and released with the proper labeling and packaging. Furthermore, no training records were documented for employees performing these operations.

OBSERVATION 8

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 failed to assign a Unique Device Identifier (UDI) to the Class II (b) (4) (b) (4) System device to rapidly identify affected devices, if a problem occurs.

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	Christopher B May, Investigator	X Christopher B May Investigator Signed By: CHRISTOPHER B. MAY -S Date Signed: 06-12-2026 14:48:15	6/12/2026

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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

Observation 8: Promised to correct

SEE REVERSE OF THIS PAGE

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X Christopher B May Investigator Signed By: CHRISTOPHER B. MAY -S Date Signed: 06-12-2026 14:48:16

DATE ISSUED
6/12/2026

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."