DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 800 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	12/1/2025-12/5/2025* FEI NUMBER 2000044808

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dennis L. Cook, CEO

FIRM NAME	STREET ADDRESS
Superior Felt & Filtration, L.L.C.	1359 Ridgeview Dr
CITY, STATE, ZIP CODE, COUNTRY Mchenry, IL 60050-7045	TYPE ESTABLISHMENT INSPECTED Contract Medical Device 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

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been established.

Specifically, your firm uses INWI7.7 RGA/Credit Work Instruction Rev 2 dated 1/4/2023 for handling and documenting complaints. INWI7.7 is applicable to all respiratory filter accessories including an accessory used with the Positive Airway Pressure (PAP) ventilator device intended to treat individuals that are diagnosed with sleep apnea conditions (K203126, Product Code: BZD). Your firm shipped approximately (b) (4) of these respiratory filter accessories in 2025. INWI7.7 is not adequate for handling complaints in that it does not include requirements for evaluating and investigating complaints. For example, RGA 25-037 was created because a customer received product that was not fully welded. An investigation was not completed even though the incomplete weld meant that the product did not meet its specification.

OBSERVATION 2

Procedures have not been adequately established to control product that does not conform to specified requirements.

Specifically, the handling of nonconforming material is governed by INQP8.3.01 Control of Non-Conforming Material Rev 7 dated 3/26/2025. INQP8.3.01 is applicable to all respiratory filter

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Chad E Schmear, Investigator X Chad E Schmear Investigator Signed By: CHAD E. SCHMEAR - S Date Signed: 12-05-2025 10:08:30	12/5/2025

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accessories including an accessory used with the Positive Airway Pressure (PAP) ventilator device intended to treat individuals that are diagnosed with sleep apnea conditions (K203126, Product Code: BZD). Your firm shipped approximately (b) (4) of these respiratory filter accessories in 2025. INQP8.3.01 has not be effectively implemented in that nonconforming material found during the filter media cutting process is not evaluated to determine the need for an investigation.

***DATES OF INSPECTION**
12/01/2025(Mon), 12/02/2025(Tue), 12/05/2025(Fri)

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Mchenry, IL 60050-7045	Contract Medical Device Manufacturer

Annotations to Observations

Observation 1: Reported corrected, not verified

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."