DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301)594-4695 Fax:(301)594-4715	10/27/2025-10/30/2025 FEI NUMBER 3013445086

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dr. Kai Opdenwinkel , General Manager

FIRM NAME	STREET ADDRESS
Freudenberg Medical Europe GmbH	Liebig Str. 2-8
CITY, STATE, ZIP CODE, COUNTRY Kaiserslautern, Rhineland-Palatinate, 67661 Germany	TYPE ESTABLISHMENT INSPECTED 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 corrective and preventive action have not been adequately established.

Specifically, an inspection of the firm's CAPA system found that the SAP database holds details necessary for inspection but are omitted from the CAPA report (the inspected record).

The CAPA procedure also:

- Lacks a clear definition of "task owner" and does not specify which documents constitute a complete CAPA record.
- Lacks clear direction on who may sign off on tasks (the task owner or a responsible owner).
- Sets a blanket 180–day completion targets regardless of each CAPA's risk level, which may be too restrictive for thorough effectiveness verification.
- Does not adequately describe and direct for a systematic method for analyzing quality data from all sources to detect potential or recurring issues.

OBSERVATION 2

Procedures to control environmental conditions have not been adequately established.

Specifically, an inspection of the cleanroom–monitoring procedures KSL–SOP–200047 "Cleanroom Monitoring" and KSL–SOP–200009 "Hygiene Management," it was noted that these procedures, collectively, do not adequately address the formulation of Non-Viable Particle Alert and Action Levels.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	John A Sciacchitano, Investigator - Dedicated Device Cadre	X	10/30/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301)594-4695 Fax:(301)594-4715	10/27/2025-10/30/2025
	FEI NUMBER 3013445086

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Dr. Kai Opdenwinkel , General Manager	
FIRM NAME Freudenberg Medical Europe GmbH	STREET ADDRESS Liebig Str. 2-8
CITY, STATE, ZIP CODE, COUNTRY Kaiserslautern, Rhineland-Palatinate, 67661 Germany	TYPE ESTABLISHMENT INSPECTED Manufacturer

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE John A Sciacchitano, Investigator - Dedicated Device Cadre	X	DATE ISSUED 10/30/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301)594-4695 Fax:(301)594-4715	10/27/2025-10/30/2025 FEI NUMBER 3013445086

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Dr. Kai Opdenwinkel , General Manager	
FIRM NAME Freudenberg Medical Europe GmbH	STREET ADDRESS Liebig Str. 2-8
CITY, STATE, ZIP CODE, COUNTRY Kaiserslautern, Rhineland-Palatinate, 67661 Germany	TYPE ESTABLISHMENT INSPECTED Manufacturer

Annotations to Observations

Observation 1:

Observation 2:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	John A Sciacchitano, Investigator - Dedicated Device Cadre	X	10/30/2025

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."