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	2/3/2026-2/10/2026* FEI NUMBER 3006076009

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Peter M. Jenkner, President

FIRM NAME	STREET ADDRESS
ISOVAC Products, LLC	1306 Enterprise Dr Ste C
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Romeoville, IL 60446-4408	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

One or more processes for risk management in product realization have not been adequately documented.

Specifically, your firm provided an incomplete risk assessment that did not have the evaluation of residual risk; lacking evaluation of risk probability of occurrence and severity ratings.

Since January 1st, 2024, your firm has manufactured (b)(4) Class II CAPSULS, K052798, a Portable Patient Isolation Unit (PIU), intended to prevent particulate (biological and radiological) cross-contamination between the patient and the external environment; and with features that enable medical intervention to the patient via end-user supplied medical equipment. The CAPSULS is intended to be used for the transport and isolation of patients on aircraft, ambulances, ships, and any vehicle capable of safely transporting a patient on a standard litter.

OBSERVATION 2

Design and development inputs related to product requirements were not determined.

Specifically, your firm could not provide design and development inputs for the functionality, performance, usability and safety requirements, according to its intended use for transporting and isolating patients on aircraft, ambulances, ships and any vehicle capable of transporting a patient on a standard litter.

Since January 1st, 2024, your firm has manufactured (b)(4) Class II CAPSULS, K052798, a Portable Patient

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Isolation Unit (PIU), intended to prevent particulate (biological and radiological) cross-contamination between the patient and the external environment; and with features that enable medical intervention to the patient via end-user supplied medical equipment.

OBSERVATION 3

Records of design and development outputs were not maintained.

Specifically, records of the design and development outputs were not maintained in the design and development file.

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OBSERVATION 4

Corrective action was not taken to eliminate the cause of nonconformities in order to prevent recurrence.

Specifically, your firm failed to initiate corrective action in response to observations documented during the previous FDA inspection. Last FDA inspection occurred from 5/08/2023-05/11/2023. No Corrective action was established to address the identified nonconformities, eliminate their root causes, or prevent recurrence. Your firm failed to follow your own CAPA procedures, Document Number 11-07-026 Effective Date 5/11/2020 Revision A, section 6.2, where it states the following: "**CAPA System**: A system for implementing corrective actions and preventative actions resulting from the investigation of complaints, product rejections, nonconformance, recalls, deviations, audits, regulatory inspections and findings, trends from process performance and product quality monitoring and management review."

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OBSERVATION 5

Purchasing information did not include a written agreement that the supplier notify your firm of changes in purchased product prior to implementation of any changes that affect the ability of purchased product to meet specified purchasing requirements.

Specifically, your firm does not have proper supplier controls, such as a supplier agreement or evaluation of suppliers to ensure critical components, such as the (b) (4) HEPA Filters; which is designed to trap at least 99.97% of airborne particles, does not undergo any changes.

Purchasing information shall include, as applicable, a written agreement that the supplier notify the organization of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements.

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OBSERVATION 6

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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 device labels do not bear a UDI.

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OBSERVATION 7

The information required by the Global Unique Device Identification Database for each medical device version or model required to bear a unique device identifier (UDI) was not provided.

Specifically, your firm has not registered The CAPSULS device with the Global Unique Device Identification Database.

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OBSERVATION 8

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Internal audits have not been conducted at planned intervals to determine whether the QMS conforms to planned and documented arrangements and applicable requirements and is effectively implemented and maintained.

Specifically, your firm failed to conduct internal audits annually, as required by your firm's internal audit procedures. Records of the audits and their results, including identification of the processes and areas audited and the conclusions, shall be maintained. However, your firm has not conducted an internal audit since 2021.

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***DATES OF INSPECTION**
2/03/2026(Tue), 2/04/2026(Wed), 2/05/2026(Thu), 2/06/2026(Fri), 2/09/2026(Mon), 2/10/2026(Tue)

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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

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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."