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	9/1/2025-9/4/2025
	FEI NUMBER 3002808464

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Bernd Marx , Deptment Quility Manager and Product Development

FIRM NAME	STREET ADDRESS
Vygon GmbH & Co. KG	Prager Ring 100
CITY, STATE, ZIP CODE, COUNTRY Aachen, North Rhine-Westphalia, 52070 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, your firm has not opened a CAPA (Corrective and Preventive Action) to address the requirements for analyzing quality data to identify existing and potential causes of complaints about products, using appropriate statistical methodology where necessary.

For example, your firm has received 362 complaints from 2024 to the present regarding leakage/tear/burst on catheter tubes, snapped catheters, and problems with the junction of the Premicath Intravascular Catheter, a Class II medical device used for venous access in premature and very low birth weight newborns who require medications, parenteral nutrition (nutritional support), or other fluid therapies, without opening a Corrective and Preventive Action (CAPA).

OBSERVATION 2

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

Specifically, your firm is not completing complaint investigations in a timely manner. Currently, the

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Clifford F Long, Investigator	X Clifford F Long Investigator Signed By: Clifford F. Long -S Date Signed: 09-04-2025 12:02:30	9/4/2025

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firm has 514 complaints on the complaint investigation log that have not been investigated. Of the 514 complaints, 133 complaints are still pending investigation from 2024, and 145 complaints from 2025 are greater than three months old.

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Annotations to Observations

Observation 1:

Observation 2:

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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."