DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Use this check box to generate the required 483 statement on page 1 for medical device observations. ☐

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Philadelphia District Office U.S. Custom House, Room 900 200 Chestnut Street Philadelphia, PA 19106 Phone 215-597-4390 Industry Information: www.fda.gov/oc/industry	03/27/2026-04/01/2026* FEI NUMBER 2523408

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Ms. Alexandra Thieroff, Senior Plant Manager

FIRM NAME	STREET ADDRESS
Linde Gas & Equipment Inc.	1 Steel Rd E
CITY, STATE AND ZIP CODE	**TYPE OF ESTABLISHMENT INSPECTED**
Morrisville, PA 19067-3613	Medical Gas Manufacturer and Repackager

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) (WE) OBSERVED:

OBSERVATION 1

The firm failed to conduct thorough and adequate annual product reviews.

Specifically,

Your document PD.OPS-0026, Revision 7, Internal Quality System Assessments and Product reviews, effective 2/2/2026, does not include specific requirements for conducting product-specific reviews of medical gases, including evaluation of batch records, testing results and stability data. Additionally, the 2023 - 2025 Quality Management reviews lacked Out-of-specification (OOS) investigations, process capability trends and change controls made during the review period for each specific product.

OBSERVATION 2

There is no written testing program designed to assess the stability characteristic of USP grade Air, (b) (4) and (b) (4)

Specifically,

Your firm has not established a stability program, nor have you performed stability studies to assess the stability characteristics of USP grade Air: (b) (4) as well as (b) (4). Currently you have manufactured, released and distributed approximately (b) (4) lots since 12/01/2025.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Luxuly Abraham -S Digitally signed by Luxuly Abraham -S Date: 2026.04.01 13:50:44 -04'00'	Luxuly Abraham, Investigator	04/01/2026

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 judgement, 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."