DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661 Industry Information: www.fda.gov/oc/industry	6/16/2026-6/18/2026
	FEI NUMBER 1312847

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Jeffery T. Taylor, Plant Manager

FIRM NAME	STREET ADDRESS
Linde Inc.	4501 Royal Ave
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Niagara Falls, NY 14303	Medical Gas 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) (WE) OBSERVED:

Observation 1: 21 CFR 213.180(d)(1)
Records are not maintained so that data therein can be reviewed at least annually to evaluate the quality standards of each medical gas to determine the need for changes in specifications or manufacturing or control procedures. Specifically,

Your firm's Annual Product Quality Review (APQR) procedure and execution are inadequate to identify trends and drive continuous improvement. For example:

A. Deficiencies in 2023 and 2025 APQRs for (b) (4) USP and (b) (4)

1. Your firm failed to review a representative number of batches in the 2023 and 2025 APQRs. Each document review of only (b) (4) batch production records, all drawn exclusively from the (b) (4) of the respective review period with an estimated (b) (4) batches produced annually.
2. Neither APQR contains any discussion of unplanned deviations, or gas out-of-specification OOS results, despite exception reports documenting such events throughout each review year. Because deviation and OOS data are siloed within individual batch records with no aggregated log or tracking system maintained at the facility level, trending across the review period is structurally hindered.

B. QAP-02.040.00, Annual Product Quality Reviews, Effective January 24, 2025

The procedure fails to define and establish evaluation to the quality standards of each medical gas to determine the need for changes in specifications or manufacturing or control procedures for:

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Lauren Augustyniak Jordan Burkdoll mla	Lauren Augustyniak, Investigator Jordan Burkdoll, Investigator Michelle Lin, Investigator	06/18/2026

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what constitutes a representative number of batch records, trending methodology, CAPA documentation, and in-process material quality data review.

Additionally, Exception Reports are only considered for review when an investigation concludes nonconforming product may have been shipped, excluding in-process OOS results and unplanned deviations that did not affect finished product release.

*DATES OF INSPECTION
6/16/2026(Tue), 6/17/2026(Wed), 6/18/2026(Thu)

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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 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."