DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	3/30/2026-4/3/2026
	FEI NUMBER 1625647

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Thomas B. Mercer, Chief Financial Officer

FIRM NAME	STREET ADDRESS
Conroe Welding Supply, Inc	4425 N Frazier S
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Conroe, TX 77301-5006	Medical Gas Repacker

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 WE OBSERVED:

Observation 1

There is no quality unit.

Specifically,
Your firm has not established, documented, or implemented an effective quality management system and current good manufacturing practice (cGMP) that involves the active participation of management, quality, and appropriate manufacturing personnel. Your firm's quality unit lacks sufficient resources to carry out its responsibilities and consistently ensure medical gas quality. For example:
A. Your firm has not designated any personnel to serve in quality assurance roles.
B. Your firm failed to establish written procedures that define the roles, responsibilities, and procedures of quality unit personnel. It was observed on batch records that the filler, tester, and product release approver were the same person, demonstrating a lack of independent verification and segregation of duties, as shown on batch records dated (b) (4) (lot (b) (4)), (b) (4) (lots (b) (4)), (b) (4) (lot (b) (4)), (b) (4) (lots (b) (4) , (b) (4)), and (b) (4) (lots (b) (4)). Your firm distributed these lots to customers.
C. Your firm failed to provide cGMP training to employees involved in cGMP manufacturing and failed to establish a standard operating procedure (SOP) for training management.
D. Your firm failed to conduct annual product reviews of medical gas being filled and distributed at your facility and failed to establish an SOP for annual product review management. Your firm has never conducted any annual product reviews of (b) (4) medical gas.
E. Your firm failed to establish SOPs for deviation, out-of-specification, investigation, and corrective action/preventive action. Your firm failed to record and maintain records of these events.
F. Your firm failed to record operational major changes. Your firm moved to a new location in February 2026, but no record of the relocation was documented and no risk assessment was conducted. Your firm failed to establish

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Timothy H Vo, Investigator Rodney L Tinzie, Investigator	X Rodney L Tinzie Investigator Signed By: 2003864377 Date Signed: 04-03-2026 11:01:29	4/3/2026

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an SOP for change control management. Additionally, after a customer complaint regarding the presence of (b) (4) gas in a medical (b) (4) vessel, your firm (b) (4) when product testing is performed; however, this change was not recorded.

G. Your firm failed to conduct internal audits and has never performed one. Your firm failed to establish an internal audit SOP.

H. Your firm failed to provide good documentation practice training to employees and failed to establish a good documentation practice SOP. It was observed that batch production records contained blackouts, overwriting, cross-outs, and corrections without dates and initials, including but not limited to batch records dated (b) (4) and (b) (4). Additionally, it was observed that some empty boxes in batch records were lined through and some were not, including but not limited to batch records dated (b) (4) (b) (4), and (b) (4).

I. Your investigation into customer complaints was inadequate. Your firm received two customer complaints in 2025; however, you did not maintain complete records of the investigations and performed incomplete investigations. Additionally, your firm's customer complaint SOP is inadequate because it does not include important elements, including but not limited to complaint investigation procedures. The SOP also lacks an effective date, version number, and reviewer/approver signature.

J. Your firm failed to conduct supplier audits and failed to establish a supplier audit management SOP. Your firm has never performed supplier audits.

K. Your recall SOP is inadequate. It does not include important elements, including but not limited to investigation procedures. Additionally, the SOP does not have an effective date, version number, or reviewer/approver signature.

L. Your firm failed to maintain records of medical gas distribution. For example, your firm could not locate records to determine whether lots (b) (4) and (b) (4), and 6 out of (b) (4) units of lo (b) (4) were distributed to customers or disposed.

M. Your firm failed to establish a preventative maintenance SOP fo (b) (4) Pumping System that used for production and the (b) (4) used for testing and failed to establish maintenance logs.

N. Your firm failed to establish a SOP for receiving bulk medical (b) (4) gas.

O. Your firm failed to establish a SOP for label control, insurance and inspection of labels.

Observation 2

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Batch production records do not include documentation that each significant step in the packaging of the medical gas was performed.

Specifically,
Source bulk (b) (4) lot numbers were not recorded on batch records dated (b) (4) (lots (b) (4) (lots (b) (4)), and (b) (4) (lots (b) (4)). These lots were distributed to customers.

Observation 3

The quality unit failed to review and approve manufacturing production and control records, including those for packaging and labeling, to determine compliance with all established, approved written procedures before batches were released or distributed.

Specifically,
The product release approver signature line was blank on batch records dated (b) (4) (lots (b) (4)), and the batches were released without any documented approval. These lots were distributed to customers.

Observation 4

Your firm failed to perform required tests on bulk medical (b) (4) USP received for production.

Specifically,

No testing was performed on any bulk lot of medical (b) (4) USP received from your supplier. Your firm has not established and maintained a program to ensure the reliability of the supplier's capabilities through appropriate assessment and testing procedures.

Observation 5

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Your firm failed to establish a written program designed to ensure proper performance of automatic, mechanical, and electronic equipment used to produce medical (b) (4)

Specifically,

The new (b) (4) equipment ((b) (4) Pumping System) used for production and the (b) (4) used for testing lack a written program to ensure proper performance and maintenance. Your firm uses this equipment to fill and test medical (b) (4) gas distributed to customers.

X Timothy H Vo
Investigator
Signed By: 2003265410
Date Signed: 04-03-2026 11:02:21

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	Timothy H Vo, Investigator Rodney L Tinzie, Investigator X Rodney L Tinzie Investigator Signed By: 2003864377 Date Signed: 04-03-2026 11:01:29	4/3/2026

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 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."