DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Suite 4-930 Cincinnati, OH 45202 (513) 322-0700 Industry Information: www.fda.gov/oc/industry	04/27/2026-04/28/2026
	FEI NUMBER 3010888324

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Steven W Troyer, Director of Operations

FIRM NAME	STREET ADDRESS
Galaxy Medical Products LLC	1133 Medina Road Ste 800
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Medina, OH 44256-5397	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

The quality control unit lacks authority to review production records to assure that no errors have occurred and fully investigate errors that have occurred.

Specifically,

Your firm failed to document and investigate the use of an out-of-calibration thermometer during the filling of (b) (4) cylinders. On 04/27/2026, an out-of-calibration thermometer (Serial # (b) (4)) hat had exceeded its calibration due date by approximately four months was observed being used during the filling of Lot (b) (4). The thermometer was used to determine cylinder fill pressure based on temperature during filling operations. No documentation, deviation, investigation, or product impact assessment was initiated to determine the effect of the out-of-calibration thermometer on product quality. Approximately (b) (4) lots have been released since Dec 2025.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	SUPREET K. SRAN -S Digitally signed by SUPREET K. SRAN -S Date: 2026.04.28 13:50:16 -04'00'	Supreet K. Sran- Investigator	04/28/2026

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."