



BAY AREA AIR QUALITY MANAGEMENT DISTRICT

PERMIT TO OPERATE

This document does not permit the holder to violate any BAAQMD regulation or any other law.

PERMIT EXPIRATION DATE

AUG 1, 2022

Plant# 24876

Infinity Labs SD
1836 Stone Avenue
San Jose, CA 95125

Location: 1836 Stone Avenue
San Jose, CA 95125

S#	DESCRIPTION	[Schedule]	PAID
1	CHEM> Sterilization, medical equipment, Ethylene oxide Ethylene Oxide Sterilizer Abated by: A1 Ethylene Oxide Catalytic Bed, Electric Emissions at: P1 Stack	[G1,373 days]	2547
2	CHEM> Sterilization, medical equipment, Ethylene oxide Ethylene Oxide Sterilizer Abated by: A2 Ethylene Oxide Catalytic Bed, Electric Emissions at: P1 Stack	[G1,373 days]	2547
3	CHEM> Sterilization, medical equipment, Ethylene oxide Ethylene Oxide Sterilizer Abated by: A2 Ethylene Oxide Catalytic Bed, Electric Emissions at: P1 Stack	[G1,373 days]	2547
4	CHEM> Sterilization, medical equipment, Ethylene oxide Ethylene Oxide Sterilizer Abated by: A1 Ethylene Oxide Catalytic Bed, Electric Emissions at: P1 Stack	[G1,373 days]	2547
5	CHEM> Sterilization, medical equipment, Ethylene oxide Ethylene Oxide Sterilizer Abated by: A3 Unclassified Abatement Device Emissions at: P1 Stack	[G1,373 days]	2547

5 Permitted Sources

*** See attached Permit Conditions ***



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*** PERMIT CONDITIONS ***

Source# Subject to Condition Numbers

1	27253
2	27253
3	27253
4	27253
5	27253

The operating parameters described above are based on information supplied by permit holder and may differ from the limits set forth in the attached conditions of the Permit to Operate. The limits of operation in the permit conditions are not to be exceeded. Exceeding these limits is considered a violation of District regulations subject to enforcement action.



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*** PERMIT CONDITIONS ***

COND# 27253 applies to S#'s 1, 2, 3, 4, 5

1. The Owner/Operator shall ensure the use of 100% ethylene oxide sterilant gas only. The use of any other sterilant gas is expressly prohibited under the terms of the permit unless prior approval and a Change of Condition is obtained in writing from the Bay Area Air Quality Management District.
[Basis: Cumulative Increase]
2. The Owner/Operator shall ensure that the total cumulative emissions of ethylene oxide sterilant gas from sources S1, S2, S3, S4, and S5 shall not exceed 0.92 pounds per consecutive twelve-month period.
[Basis: Cumulative Increase; Regulation 2, Rule 5]
3. The Owner/Operator shall ensure that the total number of sterilizer cycles (sterilization plus aeration) shall not exceed 3,640 cycles per consecutive 12-month period for all five sterilizers combined and the total usage of ethylene oxide gas does not exceed 1,364 pounds per year.
[Basis: Regulation 2, Rule 5, Section 401]
4. The Owner/Operator shall ensure that the ethylene oxide emissions from Sources S1 and S4 are controlled by A1 3M Model 50 Ethylene Oxide Catalytic Oxidizer, Sources S2 and S3 are controlled by A2 3M Model 50 Ethylene Oxide Catalytic Oxidizer, and Source S5 is controlled by A3 3M Model 50 Ethylene Oxide Catalytic Oxidizer.
[Basis: Cumulative Increase; Regulation 2, Rule 5]
5. The owner/Operator shall ensure that the sterilization cycle shall not be conducted unless ethylene oxide emissions are reduced by at least 99.99% during discharge of the sterilization phase and reduced by at least 99.90% during discharge of the aeration phase of each discrete cycle. At any time when the abatement system is unable to accept emissions from the sterilizers, the flow to the sterilizers shall automatically cease. The catalyst beds shall be replaced as needed to comply with this requirement.
[Basis: Cumulative Increase, "Ethylene Oxide ATCM for Sterilizers and Aerators", Section 93109, Title 17,



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CCR, Subsection (e)]

6. In order to demonstrate compliance with parts 2 and 3, the Owner/Operator shall maintain a log of sterilant gas purchases and the date and time of each sterilization operation cycle. These records shall be retained on site for two years after the date of purchase or entry, and shall be made available for inspection by District staff upon request.
[Basis: Cumulative Increase, Regulation 1, Rule 1-543]
7. To demonstrate compliance with these permit conditions, the Owner/Operator shall perform a District approved compliance source test (ARB Test Method 431) on each sterilizer within 60 days of sterilizer startup. The test shall include the sterilization cycle and the aeration cycle. The permit holder shall notify the Manager of the District's Source Test Section and the Director of the District's Engineering Division in writing at Least seven(7) days prior to the test, to provide District staff the option of observing testing. Within 30 days of test completion a comprehensive report of the test results shall be submitted to the Manager of the District's Source Test Section for review and disposition.
[Basis: "Ethylene Oxide ATCM for Sterilizers and Aerators", Section 93109, Title 17, CCR, Subsections (g) and (h)]
8. To demonstrate compliance with these permit conditions, the Owner/Operator also shall perform a District-approved compliance source test (ARB Test Method 431) on each sterilizer every two years. The test shall include the sterilization cycle and the aeration cycle. The Owner/Operator shall notify the Manager of the District's Source Test Section and the Director of the District's Engineering Division in writing at least Seven (7) days prior to the test, to provide District Staff the option of observing testing. Within 30 days of test completion a comprehensive report of the test results shall be submitted to the Manager of the District's Source Test Section for review and disposition. The first source test shall be due to the District on the second anniversary of the date of the



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Permit to Operate.

[Basis: "Ethylene Oxide ATCM for Sterilizers and Aerators", Section 93109, Title 17, CCR, Subsections (g) and (h)]

- 9. The Owner/Operator shall obtain approval from the District's Technical Services Division for the installation of stack sampling ports, and for all source testing procedures. The Owner/Operator shall notify the Permit Services and Technical Divisions at least two weeks prior to any source test.

[Basis: Regulation 1, Rule 1-501]

----- END OF CONDITIONS -----