



**TECHNICAL REVIEW AND EVALUATION
OF APPLICATION FOR
AIR QUALITY PERMIT No. 94533**

I. INTRODUCTION

This Class II Renewal permit is for the continued operation of Medline Industries, LP's Permit No. 94533 renews and supersedes Permit No. 66030. A Class II permit is required because of the sterilization of medical products with ethylene oxide (EtO). This permit was previously held by Centurion Medical Products Corporation. The permit was transferred to Medline Industries, LP in Administrative Amendment No. 94482 on May 18, 2022. As of the issuance date of this permit, the facility has not been in operation since December 2021.

A. Company Information

Facility Name: Medline Industries
Mailing Address: 3173 East 43rd Street
Yuma, AZ 85365
Facility Location: 3173 East 43rd Street
Yuma, AZ 85365

B. Attainment Classification

The facility is located in an area which is designated non-attainment for PM₁₀, and attainment/unclassifiable for all other criteria pollutants.

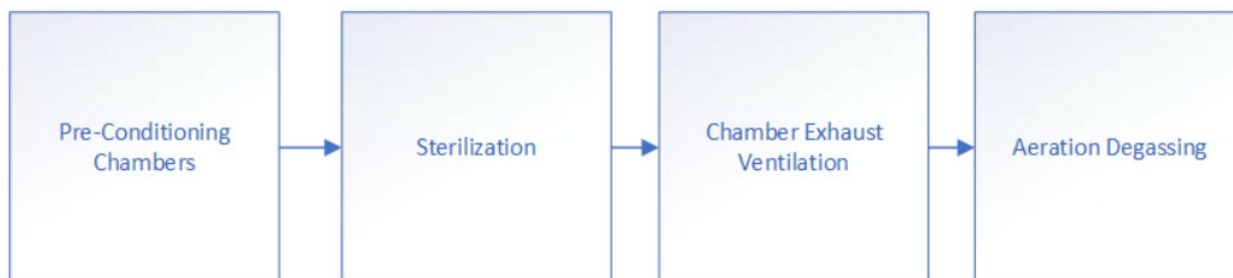
II. PROCESS DESCRIPTION

A. Process Equipment

Medline Industries operates an industrial ethylene oxide (EtO) sterilization process which consists of three stages: preconditioning, sterilization, and aeration. Prior to moving the sterilized product from the chamber to the aeration room, the door of the chamber is cracked to activate the chamber exhaust vent (CEV). The CEV ventilates the chamber for 30 minutes and serves to reduce employee exposure to EtO during the unloading process to the aeration stage.

B. Control Devices

Controlling EtO emissions is achieved in each of the three process stages. The preconditioning and sterilization stage control the high concentration of EtO through a thermal oxidizer. The CEV ventilates to five dry-bed scrubbers. The aeration room emissions are controlled with three dry-bed scrubbers.

C. Process Flow Diagram**III. COMPLIANCE HISTORY****A. Compliance Status**

A review of the compliance records for the facility indicates that there are no pending air quality cases. Within the five-year permit term for Air Quality Permit #66030, the Permittee submitted and ADEQ reviewed the following reports.

- Five annual compliance certification reports
- Nine semi-annual excess emission and continuous monitoring system performance reports (EE-MSPs) as required under NESHAP 40 CFR 63 Subpart O.

Deficiencies were noted during ADEQ's review of the compliance certification report submitted for calendar year 2021 (see Section III.B below). ADEQ noted no deficiencies with the other four compliance certifications or for the nine EE-MSP reports. The Permittee reported a deviation in the EE-MSP report submitted for the reporting period of July-December 2017 (see Section III.C below). ADEQ also conducted one full inspection in calendar years 2018, 2021, and 2022. The most recent inspection was conducted on January 25, 2022. No deficiencies were noted during the course of any of these inspections. No excess emissions were reported by the Permittee during the permit term.

B. Case Number 204133

During ADEQ's review of the Permittee's compliance certification submitted for the reporting period of January 1, 2021 through December 31, 2021 (Inspection ID: 391912), ADEQ noted that no records could be found of the semi-annual EE-MSP reports for calendar year 2021 as required under NESHAP 40 CFR 63 Subpart O. A Notice of Opportunity to Correct Deficiencies (NOC) was issued to Centurion Medical Products on April 4, 2022 that required submission of the missing EE-MSP reports. The reports were submitted on April 18 and April 20, 2022, and the NOC was closed on April 21, 2021.

C. Deviation Reported in Semi-Annual EE-MSP Report for July-December 2017 (Inspection ID 298795)

In the EE-MSP report submitted for reporting period July-December 2017, the Permittee reported that the gas chromatograph (GC) used to monitor EtO emissions from the DR-490 dry bed scrubber was down from October 8, 2017 through October 25, 2017. The GC

downtime was greater than 5% of the total operating time for the reporting period. The Permittee noted that after the quarterly maintenance on the GC, the instrument readings were erratic, indicating a malfunction of the PID lamp. The backup GC was missing the appropriate software and could not be used. During the period where repairs were made to both GCs, the dry bed media was replaced to eliminate the possibility of excess emissions. New technology with the GCs was initiated and additional maintenance checks to ensure proper functionality.

D. Performance Testing

A list of the performance tests conducted and their results is provided in Table 1:

Table 1: Performance Test Results

Emission Unit	Pollutant	Date of Test	Results of Performance Test
SCBV	EtO	08/19/2021	Pass, 99.32% destruction
ARV	EtO	08/19/2021	Pass, EtO < 1PPM
SCV	EtO	08/19/2021	Pass, 99.98% destruction
ARV	EtO	03/06/2018	Pass, EtO < 1PPM
SCV	EtO	03/06/2018	Pass, 99.99% destruction

IV. EMISSIONS

The potential-to-emit (PTE) calculations were performed using the maximum capacity and usage of the sterilization facility design as well as site-specific factors. Emissions are vented from the sterilization chamber and the aeration room. The facility is designed to utilize a thermal oxidizer to destroy EtO emissions from the sterilization chamber. The destruction efficiency of the thermal oxidizer used in the emission calculations is based on current and reproducible stack test results from August 2021 showing 99.98% destruction of EtO.

The aeration room vent and sterilization chamber back vent are designed to utilize dry-bed scrubbers to reduce EtO emissions. Emissions from the aeration room vent were estimated using the emission limit in the permit of 1 ppm from 40 CFR 63 Subpart O. The sterilization chamber back vent is not required to be controlled under 40 CFR 63 Subpart O, however Medline has chosen to reduce the EtO emissions through dry-bed scrubbers. The dry bed scrubbers have tested to destroy 99.32% EtO emissions.

Additionally, the thermal oxidizer utilizes the combustion of natural gas to destroy the EtO emissions. Emissions of nitrogen oxides (NO_x), particulate matter (PM₁₀, PM_{2.5}), carbon monoxide (CO), sulfur dioxide (SO₂), volatile organic compounds (VOCs), and lead (Pb) from the consumption of natural gas were calculated using emissions factors from the United States Environmental Protection Agency's AP-42: Fifth Edition Compilation of Emissions Factors, Volume 1: Stationary Point and Area Sources ("AP-42"), Chapter 1.4 "Natural Gas Combustion".

The facility's PTE is provided in Table 2 below:

Table 2: Potential to Emit (tpy)

Pollutant	PTE
NO _x	0.35
PM ₁₀	0.03
PM _{2.5}	0.03
CO	0.29
SO ₂	0.002
VOC	0.02
Pb	2x10 ⁻⁶
EtO (Single Greatest HAP)	0.162
Combined HAPS	0.162

V. APPLICABLE REGULATIONS

Table 3 identifies applicable regulations and verification as to why that standard applies. The table also contains a discussion of any regulations the emission unit is exempt from.

Table 3: Applicable Regulations

Unit	Control Device	Rule	Discussion
Sterilization Chambers	Thermal Oxidizer	40 CFR 63 Subpart O	These standards are applicable to the sterilization facility using ≥10 tons of ethylene oxide in any consecutive 12-month period.
Aeration Room Vent	Dry-Bed Scrubbers	40 CFR 63 Subpart O	These standards are applicable to the sterilization facility using ≥10 tons of ethylene oxide in any consecutive 12-month period.
Fugitive Dust Sources	Water Trucks, Dust Suppressants	A.A.C. R18-2 Article 6 A.A.C. R18-2-702	These standards are applicable to all fugitive dust sources at the facility.
Abrasive Blasting	Wet blasting; Dust collecting equipment; Other approved methods	A.A.C. R-18-2-702 A.A.C. R-18-2-726	These standards are applicable to any abrasive blasting operation.

Unit	Control Device	Rule	Discussion
Spray Painting	Enclosures	A.A.C. R18-2-702 A.A.C. R-18-2-727	These standards are applicable to any spray painting operation.
Demolition/Renovation Operations	N/A	A.A.C. R18-2-1101.A.8	This standard is applicable to any asbestos related demolition or renovation operations.

VI. PREVIOUS PERMIT REVISIONS AND CONDITIONS

A. Previous Permit Revisions

Table 4 provides a description of the permit revisions made to Permit No. 66030 during the previous permit term.

Table 4: Permit Revisions to Permit No. 66030

Permit Revision No.	Permit Revision Type	Brief Description
82762	Minor Permit Revision	Five additional dry-bed scrubbers were added to the sterilization chamber back ventilation to reduce EtO emissions.
94482	Administrative Amendment	Permit transferred from Centurion Medical Products Corporation to Medline Industries, LP on May 18, 2022

B. Changes to Current Renewal

Table 5 addresses the changes made to the sections and conditions from Permit No. 66030.

Table 5: Previous Permit Conditions

Section No.	Determination			Comments
	Added	Revised	Deleted	
Att. "A"		X		General Provisions: Revised to represent the most recent template language Condition XVII.D, Test plan submission changed to 14 working days.
Att. "B" Section I		X		Facility Wide Requirements: Revised to represent the most recent template language.
Att. "B" Section IV			X	Mobile Source Requirements: Section IV from the previous permit was deleted because it was determined to not be applicable.
Att. "B" Section IV		X		Other Periodic Activities: Renumbered from Section V in previous permit.
Att. "C"		X		Equipment List:

Section No.	Determination			Comments
	Added	Revised	Deleted	
				Revised to reflect the most recent equipment operating at the facility and to include equipment information provided.

VII. MONITORING, RECORDKEEPING, AND REPORTING REQUIREMENTS

Table 6 contains an inclusive but not an exhaustive list of the monitoring, recordkeeping and reporting requirements prescribed by the air quality permit. The table below is intended to provide insight to the public for how the Permittee is required to demonstrate compliance with the emission limits in the permit.

Table 6: Permit No. 94533

Emission Unit	Pollutant	Emission Limit	Monitoring Requirements	Recordkeeping Requirements	Reporting Requirements
Sterilization Chambers	EtO	99% Reduction	Performance test every 2-years	Maintain record of oxidizing temperature, performance test results, maintenance, calibrations, and inspections	Performance test results and efficiency (40 CFR 63.365(c)), annual compliance certification, semi-annual summary monitoring report
	Natural Gas Combustion	Minimum Oxidizing Temperature °F (as set by performance test)	CMS Oxidation Temperature		
Aeration Room	EtO	Max 1 ppm	Performance test every 2-years, once per hour EtO % at inlet and outlet	Maintain record of once per hour EtO % at inlet and outlet, 24-hour daily average EtO%, performance test results, maintenance, calibrations, and inspections	Performance test results and efficiency (40 CFR 63.365(d)), annual compliance certification, semi-annual summary monitoring report
Sterilization Chamber Back Ventilation	EtO	None	None	Maintain record of performance test results, maintenance, calibrations, and inspections	Annual compliance certification, semi-annual summary monitoring report
Mobile Sources	PM	40% Opacity	Instantaneous when opacity limit exceeded, followed	Maintain record of all emissions related maintenance	None

Emission Unit	Pollutant	Emission Limit	Monitoring Requirements	Recordkeeping Requirements	Reporting Requirements
			by a Method 9 observation		
Fugitive Dust	PM	40% Opacity	Instantaneous when opacity limit exceeded, followed by a Method 9 observation	Record of the dates and types of dust control measures employed, and if applicable, the results of any Method 9 observations, and any corrective action taken to lower the opacity of any excess emissions.	None
Abrasive Blasting	PM	20% Opacity	Instantaneous when opacity limit exceeded, followed by a Method 9 observation	Record the date, duration and pollution control measures of any abrasive blasting project.	None
Spray Painting	VOC	20% Opacity Control 96% of the overspray	Instantaneous when opacity limit exceeded, followed by a Method 9 observation	Maintain records of the date, duration, quantity of paint used, any applicable MSDS, and pollution control measures of any spray painting project.	None
Demolition/ Renovation	Asbestos	None	None	Maintain records of all asbestos related demolition or renovation projects including the "NESHAP Notification for Renovation and Demolition Activities" form and all supporting documents	None

VIII. LEARNING SITE EVALUATION

In accordance with ADEQ’s Environmental Permits and Approvals near Learning Sites Policy, the Department is required to conduct an evaluation to determine if any nearby learning sites would be adversely impacted by the facility. Learning sites consist of all existing public schools, charter schools and private schools the K-12 level, and all planned sites for schools approved by the Arizona School Facilities Board. The learning sites policy was established to ensure that the protection of children at learning sites is considered before a permit approval is issued by ADEQ.

This Air Quality Permit Renewal (94533) will not result in any increase in emissions as there are no changes to any equipment. Hence the facility is exempt from the learning sites evaluations. There are no learning sites in the K-12 level within a two-mile radius of the Facility.

IX. AMBIENT AIR IMPACT ANALYSIS

There are no emission increases resulting from this permit renewal and are below the permit exemption thresholds, therefore an ambient air impact analysis is not required for this renewal permit.

X. LIST OF ABBREVIATIONS

A.A.C.....	Arizona Administrative Code
ADEQ.....	Arizona Department of Environmental Quality
AERMOD.....	AMS/EPA Regulatory Model
AERMET.....	AERMOD Meteorological Preprocessor
AMS.....	American Meteorological Society
AQD.....	Air Quality Division
AQRV.....	Air Quality Related Values
ARM.....	Ambient Ratio Method
A.R.S.....	Arizona Revised Statutes
BACT.....	Best Available Control Technology
Btu/ft ³	British Thermal Units per Cubic Foot
CAM.....	Compliance Assurance Monitoring
CEMS.....	Continuous Emissions Monitoring System
CFR.....	Code of Federal Regulations
CH ₄	Methane
CO.....	Carbon Monoxide
CO ₂	Carbon Dioxide
CO ₂ e.....	CO ₂ equivalent basis
EPA.....	Environmental Protection Agency
FERC.....	Federal Energy Regulatory Commission
FLM.....	Federal Land Manager
°F.....	degrees Fahrenheit
ft.....	Feet
g.....	Gram
GHG.....	Greenhouse Gases
HAP.....	Hazardous Air Pollutant
HHV.....	Higher Heating Value
hp.....	Horsepower
hr.....	Hour

IC	Internal Combustion
kW.....	Kilowatt
MW	Megawatts
NAAQS.....	National Ambient Air Quality Standard
NO _x	Nitrogen Oxides
NO ₂	Nitrogen Dioxide
N ₂ O	Nitrous Oxide
NSPS.....	New Source Performance Standards
O ₃	Ozone
Pb	Lead
PM.....	Particulate Matter
PM10.....	Particulate Matter less than 10 µm nominal aerodynamic diameter
PM2.5.....	Particulate Matter less than 2.5 µm nominal aerodynamic diameter
PSD	Prevention of Significant Deterioration
psia.....	Pounds per square Inch (absolute)
PTE	Potential to Emit
sec	Seconds
SF ₆	Sulfur Hexafluoride
SIA.....	Significant Impact Area
SIL	Significant Impact Level
SO ₂	Sulfur Dioxide Significant Impact Levels
TPY	Tons per Year
VOC.....	Volatile Organic Compound
yr	Year