# APPLICATION PACKET
# FOR
# CLASS II PERMIT


## Arizona Department of Environmental Quality

### Air Quality Division

**1110 W. Washington St. • Phoenix, AZ 85007**
**Phone: 602-771-4106 • Email: airpermits@azdeq.gov**

SECTION 3.1

# ARIZONA DEPARTMENT OF ENVIRONMENTAL QUALITY

Air Quality Division

1110 West Washington • Phoenix, AZ 85007 • Phone: (602) 771-2338

## STANDARD CLASS II PERMIT APPLICATION FORM

(As required by A.R.S. § 49-426, and Chapter 2, Article 3, Arizona Administrative Code)

1. Permit to be issued to (Business license name of organization that is to receive permit): Centurion Medical Products

2. Mailing Address: 3173 E 43rd St

   City: Yuma State: AZ ZIP: 85365

3. Name (or names) of Responsible Official: Gabriel Montero, Juan Mendez

   Phone: 928-344-1029 Fax: Email: gmontero@medline.com

4. Facility Manager/Contact Person and Title: Gabriel Montero

   Phone: 928-344-1029 Fax: Email: gmontero@medline.com

5. Facility Name: Centurion Medical Products

   Facility Location/Address (Current/Proposed): 3173 E 43rd St

   City: Yuma County: Yuma ZIP: 85365

   Indian Reservation (if applicable, which one):

   Latitude/Longitude, Elevation: 32.649235, -114.579695

6. General Nature of Business: Warehousing & Sterilization

7. Type of Organization:

   ☒ Corporation ☐ Individual Owner ☐ Partnership ☐ Government Entity ☐ LLC

   ☐ Other

8. Permit Application Basis: ☐ New Source ☐ Revision ☒ Renewal of Existing Permit

   For renewal or modification, include existing permit number (and exp. date): 66030 Exp 10.3.22

   Date of Commencement of Construction or Modification:

   Primary Standard Industrial Classification Code: 3841

9. I certify that I have knowledge of the facts herein set forth, that the same are true, accurate and complete to the best of my knowledge and belief, and that all information not identified by me as confidential in nature shall be treated by ADEQ as public record. I also attest that I am in compliance with the applicable requirements of the Permit and will continue to comply with such requirements and any future requirements that become effective during the life of the Permit. I will present a certification of compliance to ADEQ no less than annually and more frequently if specified by ADEQ. I further state that

I will assume responsibility for the construction, modification, or operation of the source in accordance with Arizona Administrative Code, Title 18, Chapter 2 and any permit issued thereof.

Signature of Responsible Official: Gabriel Montero

Printed Name of Signer/Official Title: Gabriel Montero

Date: 4/21/22 Telephone Number: 928-344-1029

Centurion Medical Products, Corporation Chamber Exhaust Vent Improvement Project

Yuma, AZ

April, 2022

A. Detailed description of each process at the facility: Introduction to Yuma, AZ Centurion Sterilization Location

Centurion Medical Products operates an industrial ethylene oxide (EO) sterilization facility in Yuma, AZ. The facility has three sterilization chambers, one preconditioning room, and one aeration rooms. The facility sterilizes a wide range of Medical Devices as well as some pharmaceuticals and laboratory equipment.

Large portions of the medical products sterilized at the facility are sterile procedure trays that include a variety of medical devices and surgical procedure components. These procedure kits are effectively sterilized by EO due to its compatibility with a wide range of materials, relatively low heat, and ability to penetrate the complex configurations of tightly packed kits within shipper boxes and stacked on pallets. Many materials that are sensitive to higher temperatures or radiation can effectively be sterilized with EO with no impact to the product functionality or appearance.

Current Process: Following the exposure phase of an Ethylene Oxide (EtO) sterilization cycle, the EtO gas is evacuated (sterilant removal) from the chamber, followed by a series of washes. The washing process removes nearly all the EtO gas used during the sterilization cycle. The sterilant removal phase and all subsequent washes are routed via the Sterilization Chamber Vent (SCV) to a pollution control device (ZTOF) that effectively destroys greater than 99% of the EtO in the process waste stream.

Prior to moving the sterilized product from the chamber to the Aeration Room, the chamber door is cracked open to activate the Chamber Exhaust Vent (CEV), for 30 minutes prior to unloading. The CEV serves to reduce employee exposure to EtO during the unloading process.

As a proactive measure, we installed in April '21 five additional dry bed scrubbers (DR490A) to reduce EtO emissions from the CEV (Chamber Exhaust Vent) and the Containment Room floor sweeping vent at the Centurion Medical Products – Yuma AZ facility. This additional control measure reduces EtO emissions from the CEV by 99%+.

Sterilized products are then moved to the Aeration Room where they are stored for a minimum 24 hours to allow product degassing. EO laden air from this room is vented to the DR490A Dry Bed control system via the Aeration Room Vent (ARV). Emissions from this source must be reduced to a maximum 1 PPM daily average.

Process Flow:

1. Product is received by truck and then staged in the non-sterile staging area. Next, product prepped per specification, and then moved to the preconditioning room for 18 to 96 hrs residence time by forklift vehicle. The preconditioning rooms are enclosed and have insulated doors on each side which are always closed unless loading or unloading product. No ethylene oxide is used in these preconditioning rooms. The rooms are heated and humidified by steam to ensure product materials and packaging are able to be consistently and efficiently sterilized. At this point no other inputs other than steam heat and humidity have taken place. The product may spend several hours in preconditioning before moving to next steps.

2. After preconditioning of pallets of product, they are transferred to sterilization chambers for the ethylene oxide sterilization cycle. Chambers vary in size, but can accommodate different numbers of the standard size pallets. When chamber doors are closed, they are completely sealed. Sterilization process in chambers takes place under vacuum conditions. The complete seal ensures ethylene oxide does not escape the chambers.

3. Upon completion of cycle, the product is transferred to the aeration room for 24 to 120 hours of residence time. When aeration is complete, sterile product is then moved by forklift to the warehouse to prepare for shipping. Sterile product is loaded onto transportation vehicles for shipment to customers for medical use.

B. Figure 1 map layout/Flow diagram: (Included in the submission file – simplified diagram map)

C. Description of alternate operating scenarios, if applicable:

Centurion's product offering is regulated by the FDA and therefore required to have controlled processes, including a repeatable, validated sterilization process. Centurion therefore does not desire to pursue alternate operation scenarios.

D. Emissions Calculations: (see attached worksheet)

E. Minor NSR Applicability Determination: (N/A)

F. Explanation of any proposed exemption from otherwise applicable requirements:

We seek continued exemption from the fugitive dust provisions that require quarterly Method 9 observations for non-point sources of dust to assess opacity. All observation results in the past have demonstrated that opacity is at 0%. Centurion's facility in Yuma is on a small parcel and has paved parking and delivery areas. In addition, a fence is installed at the perimeter of the unimproved portion of the property to prevent unauthorized access. As a result, there is no vehicle traffic in unimproved areas of the property. It is important to note that EO sterilization is specifically excluded from opacity assessments since there is no visible effluent. Performing a quarterly opacity assessment for non-point sources is costly, burdensome and of little or no value in determining Centurion's impact on the environment.

G. Facilities that wish to accept voluntary limitations:

Not Applicable

H. Comprehensive Equipment List: (See attachment A)

I. A listing of all insignificant activities:

Not Applicable

J. Any application component that is identified as confidential shall follow the notice obligations in A.R.S. 49-432 and A.R.C. R18-2-305.

Not Applicable

K. For existing sources that are not currently in compliance:

Not Applicable.

L. Suggested draft permit language must be included in minor permit revision applications.

Not Applicable

## Emissions Inventory (EI) CY2021 - Arizona Dept of Environmental Quality (ADEQ)

### Formulas:

**Basic Formula:** $\text{Weight}_{lbs} = \frac{(C)(F)(t)(MW)}{SV \times 10E6}$

**Where:**
- **C = Concentration (ppm)**
- **F = Flow Rate (scfm)**
- **t = Time (minutes)**
- **MW = Molecular Weight (44.05 lbs/lb-mole)**
- **SV = Standard Volume (385.32 scf/lb-mole)**

### Process Parameters:

| | | | | |
|---|---|---|---|---|
| **Total Time in Calendar Year:** | 365 days or 525,600 minutes | | | |
| **Cycles Ran CY2021:** | 1320 sterilization cycles (loads) | 477 pre-upgrade | 843 post upgrade | |
| **Chamber I:** | 455 sterilization cycles (loads) or | | | |
| **Chamber J:** | 413 sterilization cycles | | | |
| **Chamber K:** | 452 sterilization cycles | | | |
| **Thermal Oxidizer Cycle Time:** | 141,040 total run time (minutes) | | | |
| **Chamber I & J:** | 100 minutes per sterilization cycle | | | |
| **Chamber K:** | 120 minutes per sterilization cycle | | | |
| **Thermal Oxidizer Destruction Efficiency:** | 99.98% proven via stack test performed by LCH (March 2018) and submitted to ADEQ | | | |
| **Natural Gas Usage Rate:** | 30 scfm (pilot - 6 scfm, assist gas - 24 scfm) | | | |
| **Number of Drums of EO used:** | 152 drums | | | |
| **Lbs of EO per Drum:** | 400 lbs of ethylene oxide per drum | | | |
| **Standard Sterilization Cycle Time:** | 8 hours per cycle | | | |
| **Aeration Room Vent (Stack #4) Flow Rate:** | 5030 scfm - this is derived from the stack test performed by LCH | | | |
| **Average Aeration Room Vent EO Concentration:** | 0.263 ppm - this data is derived from on-site monitoring | | | 0.139 |
| **Average Aeration Room EO Concentration:** | 4.032 ppm - this data is derived from on-site GC monitoring | | | 5.845 |
| **Chamber Exhaust Vent (Stack #3) Flow Rate:** | 6000 scfm - this data represents max flow rate for backvent system | | | |
| **Average Chamber Exhaust Vent Inlet EO Concentration:** | 15.3 ppm - this data derived from stack test | | | |
| **Average Chamber Exhaust Vent Outlet EO Concentration:** | 0.02 ppm - this data is derived from on-site GC monitoring | | | |
| **Average Chamber Exhaust Time:** | 30 minutes | | | |
| **Molecular Weight of Ethylene Oxide:** | 44.05 lbs/lb-mole | | | |
| **Standard Volume:** | 385.32 scf/lb-mole | | | |
| **10E6 Correction Factor:** | 1,000,000 no units | | | |

### Emissions Calculations - Hazardous Air Pollutants, HAP - Ethylene Oxide:

**Chamber Exhaust Vent (CEV):**

**Stack ID:** 3
**Equipment ID:** 401, 402 & 406

$$\text{Weight}_{tons} = \frac{(C)(F)(t)(MW)}{SV \times 10E6 \times 2000\ lbs/ton} = \frac{(15.3\ ppm)(6000\ scfm)(1320\ cycles)(30\ min)(44.05\ lbs/lb\text{-}mole)}{(385.32\ scf/lb\text{-}mole)(1{,}000{,}000)(2000\ lbs/ton)} = \mathbf{0.208}\ \text{tons EO processed}$$

Chamber I = 227.5 hours of CEV operation
Chamber J = 206.5 hours of CEV operation
Chamber K = 226 hours of CEV operation

pre-upgrade $\text{Weight}_{tons} = \frac{(C)(F)(t)(MW)}{SV \times 10E6 \times 2000\ lbs/ton} = \frac{(15.3\ ppm)(6000\ scfm)(477\ cycles)(30\ min)(44.05\ lbs/lb\text{-}mole)}{(385.32\ scf/lb\text{-}mole)(1{,}000{,}000)(2000\ lbs/ton)} = \mathbf{0.075}$ tons EO emitted or **0.017123 lbs/hr.**

post-upgrade $\text{Weight}_{tons} = \frac{(C)(F)(t)(MW)}{SV \times 10E6 \times 2000\ lbs/ton} = \frac{(0.02\ ppm)(6000\ scfm)(843\ cycles)(30\ min)(44.05\ lbs/lb\text{-}mole)}{(385.32\ scf/lb\text{-}mole)(1{,}000{,}000)(2000\ lbs/ton)} = \mathbf{0.000}$ tons EO emitted or **0.000000 lbs/hr.**

**Aeration Room Vent (ARV):**

**Stack ID:** 4
**Equipment ID:** 404 & 405

$$\text{Weight}_{tons} = \frac{(C)(F)(t)(MW)}{SV \times 10E6 \times 2000\ lbs/ton} = \frac{(4.032\ ppm)(5030\ scfm)(525{,}600\ minutes)(44.05\ lbs/lb\text{-}mole)}{(385.32\ scf/lb\text{-}mole)(1{,}000{,}000)(2000\ lbs/ton)} = \mathbf{0.609}\ \text{tons EO processed}$$

$$\text{Weight}_{tons} = \frac{(C)(F)(t)(MW)}{SV \times 10E6 \times 2000\ lbs/ton} = \frac{(0.263\ ppm)(5030\ scfm)(525{,}600\ minutes)(44.05\ lbs/lb\text{-}mole)}{(385.32\ scf/lb\text{-}mole)(1{,}000{,}000)(2000\ lbs/ton)} = \mathbf{0.040}\ \text{tons EO emitted or}\ \mathbf{0.009132\ lbs/hr.}$$

**Sterilization Chamber Vent (SCV):**

**Stack ID:** 3
**Equipment ID:** 401, 402, 403 & 406

**Weight $_{tons}$ =** (Total Weight Processed)(1 - Destruction Efficiency)

**Weight $_{tons}$ =** (Total Weight Used - CEV Weight Processed - ARV Weight Processed)(1 - Destruction Efficiency)

**Weight $_{tons}$ =** ((152 Drums of EO)(400 lbs/drum)/(2000 lbs/ton) - 0.208 tons - 0.609 tons)(1 - 0.9998)

**Weight $_{tons}$ =** → **0.006** tons EO emitted or **0.005034 lbs/hr.**

| | | | |
|---|---|---|---|
| Chamber I = | 758.3 hours of SCV operation | Chamber I = | 0.0015 tons EO emitted or 0.003869 lbs/hr. |
| Chamber J = | 688.3 hours of SCV operation | Chamber J = | 0.0010 tons EO emitted or 0.002952 lbs/hr. |
| Chamber K = | 904.0 hours of SCV operation | Chamber K = | 0.0034 tons EO emitted or 0.007597 lbs/hr. |

**Total Emissions from CEV, ARV and SCV point sources** = **0.121** total tons emitted or **241.8 lbs**

### Emissions Calculations - Emission Factors from EPA AP 42, 1.4 Natural Gas Combustion:

Total Natural Gas Used $_{mmscf}$ = $\frac{(141040\ minutes)(30\ scfm)}{(1{,}000\ scf/mscf)(1{,}000\ mscf/mmscf)}$ = 4.23 mmscf

| | | | | | | |
|---|---|---|---|---|---|---|
| Particulate Matter, PM: | 7.6 lbs/mmscf | >> | 30.10 lbs | >> | 0.016 tons | |
| Nitrogen Oxides, NOx: | 100 lbs/mmscf | >> | 396.00 lbs | >> | 0.212 tons | |
| Sulfur Oxides, SOx: | 0.6 lbs/mmscf | >> | 2.38 lbs | >> | 0.001 tons | |
| Volatile Organic Comp, VOC: | 5.5 lbs/mmscf | >> | 21.78 lbs | >> | 0.012 tons | |
| Carbon Monoxide: | 84 lbs/mmscf | >> | 332.64 lbs | >> | 0.178 tons | |
| Lead: | 0.0005 lbs/mmscf | >> | 0.002 lbs | >> | 0.002 lbs/yr | |

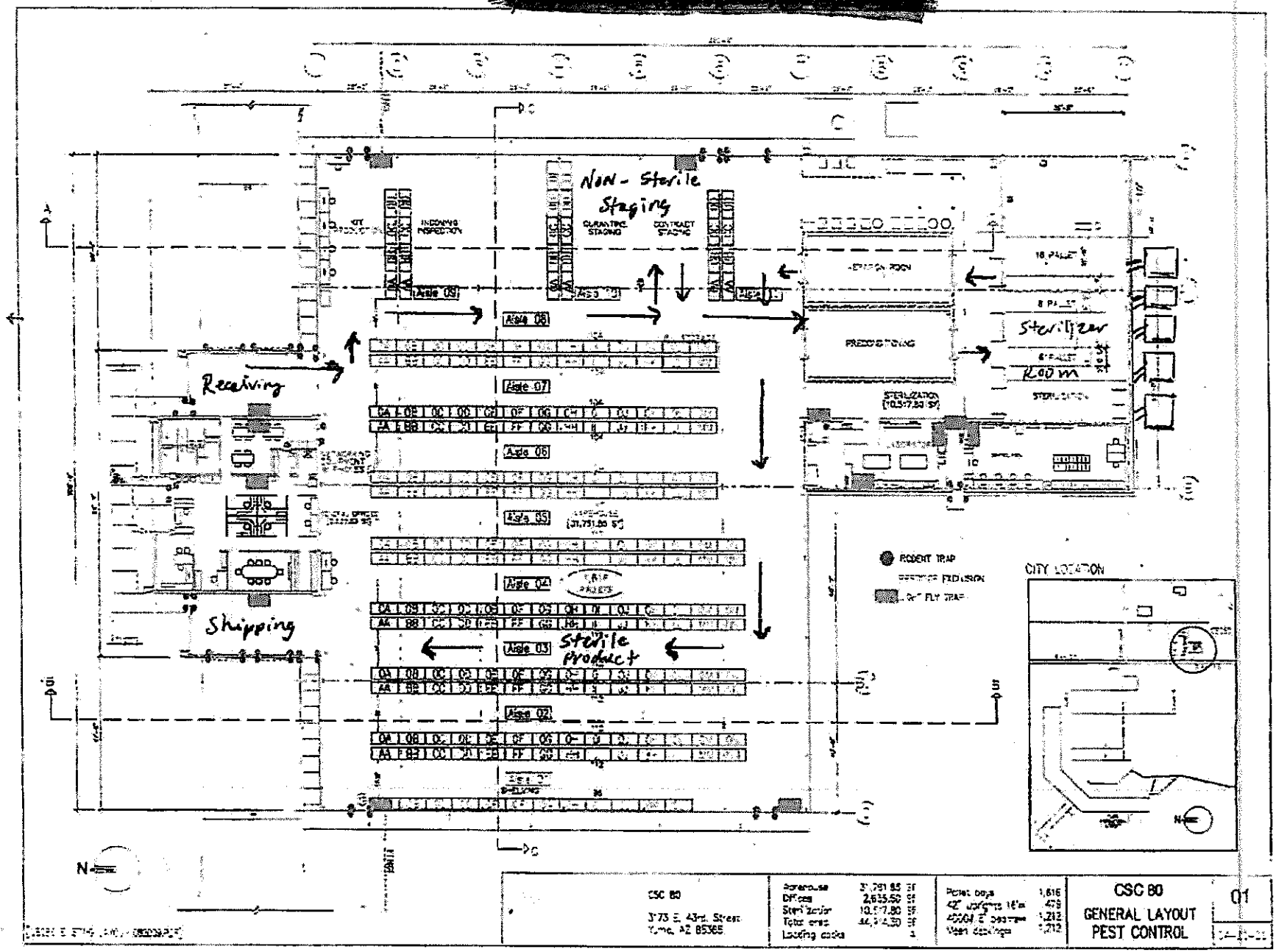
### Chamber Contribution to CEV Calculation

Chamber Volume:

| | |
|---|---|
| Chamber I: | 873 cubic ft. |
| Chamber J: | 666 cubic ft. |
| Chamber K: | 2057 cubic ft. |

| | | | |
|---|---|---|---|
| Estimated Chamber I Volume: | = (Chamber I cycles)(Chamber I chamber volume) | = | 397,215 cubic ft. |
| Estimated Chamber J Volume: | = (Chamber J cycles)(Chamber J chamber volume) | = | 275,058 cubic ft. |
| Estimated Chamber I Volume: | = (Chamber K cycles)(Chamber K chamber volume) | = | 929,764 cubic ft. |
| | Cubic feet of chamber space processed = | | 1,602,037 cubic ft. |

# Process Flow Diagram



## Section 3.5 - Equipment List

| Type of Equipment | Maximum Rated Capacity [1] | Make | Model | Serial Number | Date of Manufacture | Equipment ID Number |
|---|---|---|---|---|---|---|
| Sterilization Chamber - J | 6 pallets per cycle [1] | Vacudyne | Custom [2] | J00-23 | 2001 | 401 |
| Sterilization Chamber - I | 8 pallets per cycle [1] | Vacudyne | Custom [2] | J91-18 | 1991 | 402 |
| Thermal Oxidizer | 1650 scfm | John Zink | ZTOF | 935892-702 | 2001 | 403 |
| Dry Bed Scrubber | 6000 scfm | Advanced Air Technologies | Safe Cell II, DR490-A | NA [3] | 2001 | 404 |
| Aeration Room [4] | 80 pallets per day [5] | Onsite Facility Construction | NA [4] | NA [4] | 2001 | 405 |
| Sterilization Chamber K | 16 pallets per cycle [1] | Vacudyne | Custome [2] | J05-16 | 2006 | 406 |
| Dry Bed Scrubber [6] | 6000 cfm | Advanced Air Technologies | NA | 191278r | 2021 | 2021 |
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[1] - The duration of some of Centurion's current sterilization cycles could potentially allow up to three cycles to be processed per chamber, per day. Doing so however, exceeds the capacity of the aeration room. Therefore, two cycles per chamber per day is used for emission rate estimates.

[2] - Sterilization chambers (by Vacudyne) are manufactured specifically for Centurion Medical Products. This type of equipment is engineered to order and therefore does not have a model number.

[3] Dry bed scrubbers (by Advanced Air Technologies) are not issued serial numbers

[4] The Aeration Room is part of the facility and was constructed onsite as part of the facility construction which occurred from 2000-2002. Build date is estimated as occurring in 2001

[5] - The aeration Room can store up to 80 pallets of sterilized product at any one time. Routine aeration time is 24hrs, although exceptions exist where aeration time may last longer.

[6] - New five dry bed scrubbers were installed in 2021, these did not have model numbers and each one had the same serial number

## SECTION 3.6 - EMISSION SOURCE FORM

| | | | | | USE THIS SECTION FOR MODIFICATIONS ONLY | | |
|---|---|---|---|---|---|---|---|
| Emission Point | | Regulated Air Pollutant Name | PTE | | PTE AFTER MODIFICATION | | CHANGE IN PTE |
| Number | Name | | lbs/hr | tons/yr | lbs/hr | tons/yr | tons/yr |
| 1 | CEV - Chamber Exhaust Vent | Ethylene Oxide | .0251143 | .110 | .000913242 | .004 | |
| 2 | SEV - Sterilization Chamber Vent | Ethylene Oxide | .0011415523 | .005 | N/A | N/A | |
| 3 | ARV - Aeration Room Vent | Ethylene Oxide | .00890411 | .039 | N/A | N/A | |
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****Submit emission calculations spreadsheet with your application****

SECTION 3.1

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Air Quality Division

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7. Type of Organization:
   [X] Corporation [ ] Individual Owner [ ] Partnership [ ] Government Entity [ ] LLC
   [ ] Other
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Date: 4/21/22 Telephone Number: 928-344-1029