Covidien, LP
DeLand Facility

Facility ID No. 1270094
Volusia County

Title V Air Operation Permit Renewal

Permit No. 1270094-018-AV
(Renewal of Title V Air Operation Permit No. 1270094-016-AV)

Permitting Authority:

State of Florida
Department of Environmental Protection
Waste & Air Resource Programs, Central District

3319 Maguire Boulevard, Suite 232
Orlando, Florida 32803-3767

Telephone: (407) 897-4100
E-mail: DEP_CD@dep.state.fl.us

Compliance Authority:

State of Florida
Department of Environmental Protection
Compliance Assurance Program, Central District

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FINAL PERMIT

PERMITTEE:
Covidien, LP
2010 International Speedway Boulevard
DeLand, Florida 32724-2010

Permit No. 1270094-018-AV
DeLand Facility
Facility ID No. 1270094
Title V Air Operation Permit Renewal

The purpose of this permit is to renew the Title V air operation permit for the above referenced facility. The existing Covidien, LP facility is located in Volusia County at 2010 International Speedway Boulevard, DeLand, Florida. UTM Coordinates are: Zone 17, 474.17 km East and 3214.85 km North. Latitude is: 29˚03'42.25" North; and Longitude is: 81˚15'55.31" West.

The Title V air operation permit is issued under the provisions of Chapter 403, Florida Statutes (F.S.), and Florida Administrative Code (F.A.C.) Chapters 62-4, 62-210, 62-213. The above named permittee is hereby authorized to operate the facility in accordance with the terms and conditions of this permit.

Effective Date: October 30, 2014
Renewal Application Due Date: March 19, 2019
Expiration Date: October 30, 2019

F. Thomas Lubozynski, P.E.
Waste & Air Resource Programs Administrator

SECTION I. FACILITY INFORMATION.

Subsection A. Facility Description.

The facility is a commercial medical device manufacturing and assembly facility.

Also included in this permit are miscellaneous unregulated/insignificant emission units and/or activities.

Subsection B. Summary of Emissions Units.

EU No.	Brief Description
Regulated Emissions Units	
009	Needle Manufacturing
010	Grinding Operations

Subsection C. Applicable Regulations.

Based on the Title V air operation permit renewal application received March 17, 2014, this facility is a major source of hazardous air pollutants (HAP).

A summary of applicable regulations is shown in the following table.

Regulation	EU No(s).
State Rule Citations (62-4, 62-210.200, 62-213, 62-252, 62-296.320, and 62-297.310	All

The following conditions apply facility-wide to all emission units and activities:

FW1. Appendices. The permittee shall comply with all documents identified in Section IV, Appendices, listed in the Table of Contents. Each document is an enforceable part of this permit unless otherwise indicated. [Rule 62-213.440, F.A.C.]

Emissions and Controls

FW2. Not federally Enforceable. Objectionable Odor Prohibited. No person shall cause, suffer, allow or permit the discharge of air pollutants, which cause or contribute to an objectionable odor. An "objectionable odor" means any odor present in the outdoor atmosphere which by itself or in combination with other odors, is or may be harmful or injurious to human health or welfare, which unreasonably interferes with the comfortable use and enjoyment of life or property, or which creates a nuisance. [Rule 62-296.320(2) and 62-210.200(Definitions), F.A.C.]

FW3. General Volatile Organic Compounds (VOC) Emissions or Organic Solvents (OS) Emissions. The permittee shall allow no person to store, pump, handle, process, load, unload or use in any process or installation, volatile organic compounds or organic solvents without applying known and existing vapor emission control devices or systems deemed-necessary and ordered by the Department. To comply, procedures to minimize pollutant emissions shall include the following:

a. tightly cover or close all VOC containers when they are not in use,
b. tightly cover, where possible, all open troughs, basins, baths, tanks, etc. when they are not in use,
c. maintain all piping, valves, fittings, etc. in good operating condition,
d. prevent excessive air turbulence across exposed VOC's,
e. immediately confine and clean up VOC spills and make sure certain wastes are placed in closed containers for reuse, recycling or proper disposal.

[Rule 62-296.320(1), F.A.C. and Construction Permit 1270173-001-AC, dated July 22, 1996]

FW4. General Visible Emissions. No person shall cause, let, permit, suffer or allow to be discharged into the atmosphere the emissions of air pollutants from any activity equal to or greater than 20% opacity. EPA Method 9 is the method of compliance pursuant to Chapter 62-297, F.A.C. This regulation does not impose a specific testing requirement. [Rule 62-296.320(4)(b)1. and 4., F.A.C.]

FW5. Unconfined Particulate Matter. No person shall cause, let, permit, suffer or allow the emissions of unconfined particulate matter from any activity, including vehicular movement; transportation of materials; construction; alteration; demolition or wrecking; or industrially related activities such as loading, unloading, storing or handling; without taking reasonable precautions to prevent such emissions. Reasonable precautions to prevent emissions of unconfined particulate matter at this facility include:

a. use of hoods, fans and filters to collect and contain particulate matter generated by grinding operations.
b. use of filters to collect and contain particulate matter from conveying of plastic chips for molding operations,
c. Landscaping or planting of vegetation; and,
d. application of water as needed during construction activities on-site
e. Other techniques as necessary

[Rule 62-296.320(4)(c)1. and 2., F.A.C.; and, proposed by applicant in Title V air operation permit application received March 17, 2013.]

Annual Facility-wide Reports and Fees

See Appendix RR, Facility-wide Reporting Requirements for additional details.

FW6. Electronic Annual Operating Report and Title V Annual Emissions Fees. The information required by the Annual Operating Report for Air Pollutant Emitting Facility [Including Title V Source Emissions Fee Calculation] (DEP Form No. 62-210.900(5)) shall be submitted by April 1 of each year, for the previous calendar year, to the Department of Environmental Protection's Division of Air Resource Management. Each Title V source shall submit the annual operating report using the DEP's Electronic Annual Operating Report (EAOR) software, unless the Title V source claims a technical or financial hardship by submitting DEP Form No. 62-210.900(5) to the DEP Division of Air Resource Management instead of using the reporting software. Emissions shall be computed in accordance with the provisions of subsection 62-210.370(2), F.A.C. Each Title V source must pay between January 15 and April 1 of each year an annual emissions fee in an amount determined as set forth in subsection 62-213.205(1), F.A.C. The annual fee shall only apply to those regulated pollutants, except carbon monoxide and greenhouse gases, for which an allowable numeric emission-limiting standard is specified in the source's most recent construction permit or operation permit. Upon completing the required EAOR entries, the EAOR Title V Fee Invoice can be printed by the source showing which of the reported emissions are subject to the fee and the total Title V Annual Emissions Fee that is due. The submission of the annual Title V emissions fee payment is also due (postmarked) by April 1st of each year. A copy of the system-generated EAOR Title V Annual Emissions Fee Invoice and the indicated total fee shall be submitted to: **Major Air Pollution Source Annual Emissions Fee, P.O. Box 3070, Tallahassee, Florida 32315-3070.** Additional information is available by accessing the Title V Annual Emissions Fee On-line Information Center at the following Internet web site: http://www.dep.state.fl.us/air/emission/tvfee.htm. [Rules 62-210.370(3), 62-210.900 & 62-213.205, F.A.C.; and, §403.0872(11), Florida Statutes (2013)]

{Permitting Note: Resources to help you complete your AOR are available on the electronic AOR (EAOR) website at: http://www.dep.state.fl.us/air/emission/eaor. If you have questions or need assistance after reviewing the information posted on the EAOR website, please contact the Department by phone at (850) 717-9000 or email at eaor@dep.state.fl.us.}

{Permitting Note: The Title V Annual Emissions Fee form (DEP Form No. 62-213.900(1)) has been repealed. ***A separate Annual Emissions Fee form is no longer required to be submitted by March 1st each year.****}*

FW7. Annual Statement of Compliance. The permittee shall submit an annual statement of compliance to the compliance authority at the address shown on the cover of this permit within 60 days after the end of each calendar year (that is, March 1st) during which the Title V permit was effective. The submittal may be made electronically to **DEP_CD@dep.state.fl.us**. [Rules 62-213.440(3)(a)2. & 3. and (3)(b), F.A.C.]

FW8. Prevention of Accidental Releases (Section 112(r) of the Clean Air Act). If and when the facility becomes subject to Section 112(r), the permittee shall:

a. Submit its Risk Management Plan (RMP) to the Chemical Emergency Preparedness and Prevention Office (CEPPO) RMP Reporting Center.
   i. Any Risk Management Plans, original submittals, revisions or updates to submittals, should be sent to: RMP Reporting Center, Post Office Box 10162, Fairfax, VA 22038, Telephone: (703) 227-7650, or by e-mail RMPRC@epacdx.net.
   ii. According to the following hyperlink, the RMP can be submitted electronically: http://www.epa.gov/emergencies/content/rmp/index.htm#submitting

[40 CFR 68]

Subsection A. Emission Units 009 and 010

The specific conditions in this section apply to the following emissions unit:

EU No.	Brief Description
009	Needle Manufacturing – Needle manufacturing includes needle/device assembly machines, needle lube mixing sterilization, packaging and testing operations. VOC and HAP emissions are from materials used in the needle lube prep, gluing, assembly and other operations conducted throughout the facility.
010	Grinding Operations – Grinding operations include wet blast, grit blast and electrolytic grinding operations. Particulate matter is controlled by use of cyclones and wet scrubbers at areas of grinding operations in the facility.

Essential Potential to Emit (PTE) Parameters

A.1. Hours of Operation: The hours of operation are not limited (8,760 hours/year). [Rule 62-210.200(247) (Potential to Emit), F.A.C, Permit No. 1270094-014-AC, dated July 22, 1996]

Emission Limitations and Standards

A.2. Visible Emissions: Visible emissions shall not exceed 20% opacity. [Rule 62-296.320(4)(b)1, F.A.C]

A.3. VOC and HAP Emissions Standards – As proposed by the Applicant, the maximum facility total VOC, total HAPs, and individual HAP emissions from this facility shall not exceed the following limits.

Pollutant	**Maximum Emissions Rate** (Tons Per Any Consecutive 12-month period)
VOC Emissions (including any clean-up solvents)	Less than 75
Total HAP Emissions	Less than 60
Individual HAP Emissions	Less than 60

[Permit Application dated January 2, 2014, Operating Permit 1270094-016-AV dated October 24, 2012, and Rule 62-210.200(247) "Potential to Emit", F.A.C.]

{Permitting note: Construction Permit 1270094-017-AC, dated 02/27/14, authorized installation of an additional needle manufacturing line at the facility and increased facility-wide VOC limits to 82 TPY, and HAP and individual HAP limits to 65 TPY to allow for additional emissions once construction of that new manufacturing line is completed. In accordance with the Construction Permit, the applicant will revise the Title V permit once installation of the new production line is completed and line is operational.

Although particulate matter (PM) emissions are not limited, the use of PM control devices (cyclones and wet scrubbers as described in the permit application and supporting emission calculations) are required so that the facility's PM emissions are less than the threshold limits required for the facility to be considered a major source per Chapter 62-213, F.A.C.}

Recordkeeping Compliance Demonstration Requirements

A.4. Monthly Log: In order to demonstrate compliance with Specific Condition **A.3,** the permittee shall maintain a monthly log at the facility for a period of at least five years from the date the data is recorded

The monthly summary of the log, at a minimum, shall contain the following:

1. Facility Name, Facility ID No. (i.e., Facility Name, Facility # 1270094);
2. Designation of the month and year of operation for which the records are being tabulated;
3. Most recent monthly total of VOC emissions, total HAP emissions, and individual HAP emissions;
4. Consecutive 12-month total of total VOC emissions; total HAP emissions and each individual HAP emissions in tons.

The monthly logs shall be completed no later than the end of the following month.

Note: A consecutive 12-month total is equal to the total for the month in question plus the totals for the eleven months previous to the month in question. A consecutive 12-month total treats each month of the year as the end of a 12-month period. A 12-month total is not a year-to-date total. Facilities that have not been operating for 12 months should retain 12-month totals using whatever number of months of data is available until such a time as a consecutive 12-month total can be maintained each month.
[Rule 62-4.070(3) and Chapter 62-210, F.A.C.]

A.5. Additional Recordkeeping Requirements: Records specified in Specific Condition No. **A.4.** (previous condition) must document the method, calculations, and formulas used in determining the usage rate and the emission rate. All calculations, including those used to derive emissions, must be clearly documented, and may be presented in the form of a template of sample calculations and available for review on site by the Department.
[Rule 62-4.070(3), F.A.C.]

A.6. Supporting Documentation: Supporting documentation (chemical usage tracking logs, "As Supplied" sheets, Safety Data Sheets, EPA data sheets, purchase orders, waste shipment/disposal records, etc.) shall be kept for each chemical and associated products. The supporting documentation must include sufficient information to determine usage rates and emissions for a minimum of five (5) years. The documents must be made available to the Department upon request. Documentation of each chemical reclaimed will use a mass balance method to determine usage/emissions (amount used minus amount collected for disposal or recycle).
[Rule 62-4.070(3), F.A.C.]

A.7. Record Retention: The records required in Specific Condition No. **A.4.** shall be recorded in a permanent form suitable for inspection and made available to the Department upon request. The records shall be maintained onsite for a minimum of five (5) years.
[Rule 62-4.070(3), F.A.C.]

SECTION IV. APPENDICES.

The Following Appendices Are Enforceable Parts of This Permit:

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Appendix A, Glossary.
Appendix I, List of Insignificant Emissions Units and/or Activities
Appendix RR, Facility-wide Reporting Requirements.
Appendix TV, Title V General Conditions.

The following Attachment is for Information only
Table H, Permit History.